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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 AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

[Docket No. FCIC–17–0003]

RIN 0563–AC59

Common Crop Insurance Regulations; Cultivated Clam Crop Insurance Provisions

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule with request for comments; correcting amendment.

SUMMARY: This document contains necessary amendments to apply a technical correction to the final rule with request for comments for the Cultivated Clam Crop Insurance Provisions which published in the **Federal Register** on December 27, 2017.

DATES: *Effective Date:* April 17, 2018.

FOR FURTHER INFORMATION CONTACT: Ron Lundine, Director, Product Management, Actuarial and Product Design Division, Risk Management Agency, United States Department of Agriculture, Beacon Facility, Stop 0812, Room 421, P.O. Box 419205, Kansas City, MO 64141–6205, telephone (816) 926–3854.

SUPPLEMENTARY INFORMATION:

Background

This technical correction is being published to remove section 15 of the ''cultivated clam crop insurance provisions,'' published December 27, 2017 (Docket No. FCIC–17–0003). Section 15 excludes the use of written agreements by not allowing the written agreement provisions in the Common Crop Insurance Policy Basic Provisions to apply. This provision was necessary when the program was a pilot program to ensure there were no changes made to the policy so that the existing terms would be evaluated to make sure they were actuarially sound and there were no program integrity issues. Once the pilot program is completed, evaluated, and approved for permanence, the restriction on written agreements is no longer necessary. As a result of the removal of section 15, FCIC is allowing the use of written agreements under the cultivated clam crop provisions and redesignating subtitle numbering from section 16 to section 15, section 17 to section 16, and section 18 to section 17.

List of Subjects in 7 CFR Part 457

Crop insurance, Cultivated clam, Reporting and recordkeeping requirements.

Accordingly, 7 CFR part 457 is corrected by making the following amendments:

PART 457—COMMON CROP INSURANCE REGULATIONS

■ 1. The authority citation for 7 CFR part 457 continues to read as follows:

Authority: 7 U.S.C. 1506(l) and 1506(o).

§ 457.176 [Amended]

■ 2. Amend § 457.176, in the cultivated clam crop insurance provisions, by removing section 15 and redesignating sections 16 through 18 as sections 15 through section 17.

Signed in Washington, DC, on April 12, 2018.

Heather Manzano,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 2018–08017 Filed 4–16–18; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

[Docket No. FCIC–17–0002]

RIN 0563–AC58

Common Crop Insurance Regulations; California Avocado Crop Insurance Provisions

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Correcting amendment.

SUMMARY: This document contains necessary amendments to apply a technical correction to the final rule with request for comments for the California Avocado Crop Insurance Provisions which published in the **Federal Register** on December 27, 2017.

DATES: *Effective Date:* April 17, 2018.

FOR FURTHER INFORMATION CONTACT: Ron Lundine, Director, Product Management, Actuarial and Product Design Division, Risk Management Agency, United States Department of Agriculture, Beacon Facility, Stop 0812, Room 421, P.O. Box 419205, Kansas City, MO 64141–6205, telephone (816) 926–3854.

SUPPLEMENTARY INFORMATION:

Background

This technical correction is being published to remove section 13 of the ''California avocado crop insurance provisions,'' published December 27, 2017 (Docket No. FCIC–17–0002). Section 13 excludes the use of written agreements by not allowing the written agreement provisions in the Common Crop Insurance Policy Basic Provisions to apply. This provision was necessary when the program was a pilot program to ensure there were no changes made to the policy so that the existing terms would be evaluated to make sure they were actuarially sound and there were no program integrity issues. Once the pilot program is completed, evaluated, and approved for permanence, the restriction on written agreements is no longer necessary. As a result of the removal of section 13, FCIC is allowing the use of written agreements under the California avocado crop provisions and redesignating subtitle numbering from section 14 to section 13.

List of Subjects in 7 CFR Part 457

Crop insurance, California avocado, Reporting and recordkeeping requirements.

Accordingly, 7 CFR part 457 is corrected by making the following amendments:

PART 457—COMMON CROP INSURANCE REGULATIONS

■ 1. The authority citation for part 457 continues to read as follows:

Authority: 7 U.S.C. 1506(l) and 1506(o).

§ 457.175 [Amended]

■ 2. Amend § 457.175, in the California avocado crop provisions, by removing section 13 and redesignating section 14 as section 13.

Signed in Washington, DC, on April 12, 2018.

Heather Manzano,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 2018–08016 Filed 4–16–18; 8:45 am]

BILLING CODE 3410–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0299; Product Identifier 2018–NM–060–AD; Amendment 39–19256; AD 2018–08–03]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for The Boeing Company Model 787–8 and 787–9 airplanes powered by Rolls-Royce plc (RR) Trent 1000–A2, Trent 1000–AE2, Trent 1000–C2, Trent 1000–CE2, Trent 1000–D2, Trent 1000–E2, Trent 1000–G2, Trent 1000–H2, Trent 1000–J2, Trent 1000–K2, and Trent 1000–L2 turbofan engines. This AD requires revising the airplane flight manual to limit extended operations (ETOPS). This AD was prompted by a report from the engine manufacturer indicating that after an engine failure, prolonged operation at high thrust settings on the remaining engine during an ETOPS diversion may result in failure of the remaining engine before the diversion can be safely completed. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 17, 2018.

We must receive comments on this AD by June 1, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0299; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tak Kobayashi, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th Street, Des Moines, WA 98198; phone and fax: 206–231–3553; email: *Takahisa.Kobayashi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

Over the past year, we have been aware of several engine failures of Trent 1000 Package C engines due to failed compressor and turbine blades and seals. Package C engines are Rolls-Royce plc (RR) Trent 1000–A2, Trent 1000–AE2, Trent 1000–C2, Trent 1000–CE2, Trent 1000–D2, Trent 1000–E2, Trent 1000–G2, Trent 1000–H2, Trent 1000–J2, Trent 1000–K2, and Trent 1000–L2 turbofan engines. During that same period, under the management programs for those engine issues, we have been aware of numerous reports of engine inspection findings of cracked blades resulting in unscheduled engine removals. Boeing reported to the FAA that the engine manufacturer recently determined that intermediate pressure compressor (IPC) stage 2 blades have a resonant frequency that is excited by the airflow conditions existing in the engine during operation at high thrust settings under certain temperature and altitude conditions. The resultant blade vibration can result in cumulative fatigue damage that can cause blade failure and consequent engine shutdown. In the event of a single engine in-flight shutdown during the cruise phase of flight, thrust on the remaining engine is normally increased to maximum continuous thrust (MCT). During a diversion following a single engine shutdown under an ETOPS flight, the remaining engine may operate at MCT for a prolonged period, under which the IPC stage 2 blades would be exposed to the resonant frequency condition. Therefore, an ETOPS diversion will put the remaining engine at an operating condition that would significantly increase the likelihood of failure of the remaining engine. In addition, if the remaining engine already had cracked IPC stage 2 blades, the likelihood of the remaining engine failing will further increase before a diversion can be safely completed.

FAA's Determination

We are issuing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

AD Requirements

This AD requires revising the AFM to limit ETOPS operation.

Interim Action

This AD is interim action. The manufacturer is currently developing a modification that will address the unsafe condition identified in this AD. Once this modification is developed, approved, and available, we might consider additional rulemaking.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because unrecoverable thrust loss on both engines could lead to a forced landing. Therefore, we find good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reasons stated above, we find that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, we invite you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA–2018–0299 and Product Identifier 2018–NM–060–AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this final rule. We will consider all comments received by the

closing date and may amend this final rule because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this final rule.

Costs of Compliance

We estimate that this AD affects 14 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
AFM revisions	1 work-hour × $85 per hour = $85	$0	$85	$1,190

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2018–08–03 The Boeing Company: Amendment 39–19256; Docket No. FAA–2018–0299; Product Identifier 2018–NM–060–AD.

(a) Effective Date

This AD is effective April 17, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787–8 and 787–9 airplanes, certificated in any category, powered by Rolls-Royce plc (RR) Trent 1000–A2, Trent 1000–AE2, Trent 1000–C2, Trent 1000–CE2, Trent 1000–D2, Trent 1000–E2, Trent 1000–G2, Trent 1000–H2, Trent 1000–J2, Trent 1000–K2, and Trent 1000–L2 turbofan engines.

(d) Subject

Air Transport Association (ATA) of America Code 71, Power plant.

(e) Unsafe Condition

This AD was prompted by a report from the engine manufacturer indicating that after an engine failure, prolonged operation at high thrust settings on the remaining engine during an extended-operation (ETOPS) diversion may result in failure of the remaining engine before the diversion can be safely completed. We are issuing this AD to address unrecoverable thrust loss on both engines, which could lead to a forced landing.

(f) Compliance

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

(g) Revision of Limitations Chapter in Airplane Flight Manual (AFM)

Within 3 days after the effective date of this AD, revise the Certificate Limitations chapter of the applicable Boeing AFM Engine Appendix by incorporating the information in figure 1 to paragraph (g) of this AD. Where figure 1 to paragraph (g) of this AD refers to a ''Trent 1000 2 engine,'' this term means all engines identified in paragraph (c) of this AD. This may be accomplished by inserting a copy of this AD into the AFM. When information identical to that in figure 1 to paragraph (g) of this AD has been included in the Certificate Limitations chapter of the general revisions of the AFM, the general revisions may be inserted into the AFM, and the copy of this AD may be removed from the AFM.

Figure 1 to paragraph (g) of this AD – *AFM Certificate Limitations*

Engine Appendix - Certificate Limitations (Required by AD 2018-08-03)

ETOPS

The following information applies to 787-8 and 787-9 airplanes equipped with a RR Trent 1000 series engine that has a numeral "2" at the end of the model number installed on either wing, and that has 300 or more total accumulated engine flight cycles.

To ensure continued safe flight during ETOPS, planned aircraft gross weight must not exceed those specified in the ETOPS Section of the Performance Chapter prior to operating more than 60 minutes from a suitable airport.

ETOPS Diversion Speeds and Times

ETOPS Single Engine Driftdown diversion must be planned and flown at Engine-Out Long Range Cruise speed. Maximum diversion time for single engine driftdown must not exceed 140 minutes.

ETOPS Decompression diversion at 10,000 feet must be planned and flown at Mach 0.55. For intermediate altitude level offs above 10,000 feet, Long Range Cruise speed must be used.

(h) Revision of Performance Chapter of AFM

Concurrently with accomplishment of the requirements of paragraph (g) of this AD, revise the Performance chapter of the applicable Boeing AFM Engine Appendix by incorporating the information in figure 2 to paragraph (h) of this AD. This may be accomplished by inserting a copy of this AD into the AFM. When information identical to that in figure 2 to paragraph (h) of this AD has been included in the Performance chapter of the general revisions of the AFM, the general revisions may be inserted into the AFM, and the copy of this AD may be removed from the AFM.

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Figure 2 to paragraph (h) of this AD – *AFM Performance*

Engine Appendix – Performance

ETOPS

ETOPS operation of a Model 787-8 or 787-9 airplane equipped with a RR Trent 1000 A2, C2, or E2 series engine is prohibited.

As outlined in the ETOPs Section of the Certificate Limitations Chapter, the following table must be utilized when planning ETOPS flights.

(D631Z003-9R64EF) 787-9 Trent 1000-AE2

		Enroute Diversion Temperature					
		ISA+0 Degrees C and Below	ISA+10 Degrees C	ISA+15 Degrees C	ISA+20 Degrees C	ISA+25 Degrees C	Above ISA+25 Degrees C
Minimum Engine-Out Cruise Altitude (ft)		19,000	19,000	18,800	18,500	18,300	Prohibited
Maximum Planned Weight at ETOPS Entry Point without Forecast Icing	LBS	499,000	497,400	477,500	453,000	428,400	Prohibited
	KGS	226,360	225,650	216,620	205,480	194,350	
Maximum Planned Weight at ETOPS Entry Point with Forecast Icing	LBS	425,900	417,000	396,300	367,300	338,200	Prohibited
	KGS	193,210	189,170	179,800	166,610	153,420	

(D631Z003-9R7072F) and (D631Z003- 9R7072E) 787-9 Trent 1000-D2

		Enroute Diversion Temperature					
		ISA+0 Degrees C and Below	ISA+10 Degrees C	ISA+15 Degrees C	ISA+20 Degrees C	ISA+25 Degrees C	Above ISA+25 Degrees C
Minimum Engine-Out Cruise Altitude (ft)		19,100	19,100	18,900	18,700	18,500	Prohibited
Maximum Planned Weight at ETOPS Entry Point without Forecast Icing	LBS	510,300	508,400	488,200	465,800	443,400	Prohibited
	KGS	231,500	230,640	221,480	211,310	201,130	
Maximum Planned Weight at ETOPS Entry Point with Forecast Icing	LBS	438,300	429,300	408,400	383,800	359,300	Prohibited
	KGS	198,830	194,760	185,240	174,110	162,970	

(D631Z003-9R74F) and (D631Z003-9R74E) 787-9 Trent 1000-J2

		Enroute Diversion Temperature					
		ISA+0 Degrees C and Below	ISA+10 Degrees C	ISA+15 Degrees C	ISA+20 Degrees C	ISA+25 Degrees C	Above ISA+25 Degrees C
Minimum Engine-Out Cruise Altitude (ft)		19,300	19,300	19,100	18,800	18,500	Prohibited
Maximum Planned Weight at ETOPS Entry Point without Forecast Icing	LBS	530,400	527,800	507,800	479,500	451,100	Prohibited
	KGS	240,600	239,430	230,370	217,510	204,640	
Maximum Planned Weight at ETOPS Entry Point with Forecast Icing	LBS	455,200	446,600	430,200	401,400	372,500	Prohibited
	KGS	206,470	202,580	195,140	182,070	169,000	

(D631Z003-R7475F) and (D631Z003-R7475E) 787-9 Trent 1000-K2

		Enroute Diversion Temperature					
		ISA+0 Degrees C and Below	ISA+10 Degrees C	ISA+15 Degrees C	ISA+20 Degrees C	ISA+25 Degrees C	Above ISA+25 Degrees C
Minimum Engine-Out Cruise Altitude (ft)		19,300	19,300	19,100	18,800	18,500	Prohibited
Maximum Planned Weight at ETOPS Entry Point without Forecast Icing	LBS	530,400	527,800	507,800	479,500	451,100	Prohibited
	KGS	240,600	239,430	230,370	217,510	204,640	
Maximum Planned Weight at ETOPS Entry Point with Forecast Icing	LBS	455,200	446,600	430,200	401,400	372,500	Prohibited
	KGS	206,470	202,580	195,140	182,070	169,000	

(D631Z003-R70EF) 787-8 Trent 1000-CE2

		Enroute Diversion Temperature					
		ISA+0 Degrees C and Below	ISA+10 Degrees C	ISA+15 Degrees C	ISA+20 Degrees C	ISA+25 Degrees C	Above ISA+25 Degrees C
Minimum Engine-Out Cruise Altitude (ft)		19,300	19,300	19,100	18,900	18,600	Prohibited
Maximum Planned Weight at ETOPS Entry Point without Forecast Icing	LBS	525,100	523,100	501,400	476,300	451,100	Prohibited
	KGS	238,200	237,310	227,450	216,040	204,630	
Maximum Planned Weight at ETOPS Entry Point with Forecast Icing	LBS	446,700	438,600	419,400	396,300	373,300	Prohibited
	KGS	202,650	198,970	190,260	179,790	169,330	

(D631Z003-R7072F) and (D631Z003-R7072E) 787-8 Trent 1000-D2

		Enroute Diversion Temperature					
		ISA+0 Degrees C and Below	ISA+10 Degrees C	ISA+15 Degrees C	ISA+20 Degrees C	ISA+25 Degrees C	Above ISA+25 Degrees C
Minimum Engine-Out Cruise Altitude (ft)		19,300	19,300	19,100	18,900	18,600	Prohibited
Maximum Planned Weight at ETOPS Entry Point without Forecast Icing	LBS	525,100	523,100	501,400	476,300	451,100	Prohibited
	KGS	238,200	237,310	227,450	216,040	204,630	
Maximum Planned Weight at ETOPS Entry Point with Forecast Icing	LBS	446,700	438,600	419,400	396,300	373,300	Prohibited
	KGS	202,650	198,970	190,260	179,790	169,330	

(D631Z003-R70LF) 787-8 Trent 1000-L2

		Enroute Diversion Temperature					
		ISA+0 Degrees C and Below	ISA+10 Degrees C	ISA+15 Degrees C	ISA+20 Degrees C	ISA+25 Degrees C	Above ISA+25 Degrees C
Minimum Engine-Out Cruise Altitude (ft)		19,300	19,300	19,100	18,900	18,600	Prohibited
Maximum Planned Weight at ETOPS Entry Point without Forecast Icing	LBS	525,100	523,100	501,400	476,300	451,100	Prohibited
	KGS	238,200	237,310	227,450	216,040	204,630	
Maximum Planned Weight at ETOPS Entry Point with Forecast Icing	LBS	446,700	438,600	419,400	396,300	373,300	Prohibited
	KGS	202,650	198,970	190,260	179,790	169,330	

(D631Z003-R67F) and (D631Z003-R67E) 787-8 Trent 1000-G2

		Enroute Diversion Temperature					
		ISA+0 Degrees C and Below	ISA+10 Degrees C	ISA+15 Degrees C	ISA+20 Degrees C	ISA+25 Degrees C	Above ISA+25 Degrees C
Minimum Engine-Out Cruise Altitude (ft)		19,200	19,200	19,000	18,700	18,400	Prohibited
Maximum Planned Weight at ETOPS Entry Point without Forecast Icing	LBS	512,800	511,100	488,900	461,500	434,100	Prohibited
	KGS	232,600	231,860	221,780	209,340	196,910	
Maximum Planned Weight at ETOPS Entry Point with Forecast Icing	LBS	436,300	426,700	405,700	383,400	361,100	Prohibited
	KGS	197,910	193,550	184,020	173,910	163,810	

(D631Z003-R64EF) and (D631Z003-R64EE) 787-8 Trent 1000-AE2

		Enroute Diversion Temperature					
		ISA+0 Degrees C and Below	ISA+10 Degrees C	ISA+15 Degrees C	ISA+20 Degrees C	ISA+25 Degrees C	Above ISA+25 Degrees C
Minimum Engine-Out Cruise Altitude (ft)		19,200	19,200	19,000	18,700	18,400	Prohibited
Maximum Planned Weight at ETOPS Entry Point without Forecast Icing	LBS	512,800	511,100	488,900	461,500	434,100	Prohibited
	KGS	232,640	231,870	221,770	209,340	196,900	
Maximum Planned Weight at ETOPS Entry Point with Forecast Icing	LBS	436,200	426,600	405,600	383,400	361,100	Prohibited
	KGS	197,860	193,500	184,020	173,910	163,810	

(D631Z003-R58F) 787-8 Trent 1000-H2

		Enroute Diversion Temperature					
		ISA+0 Degrees C and Below	ISA+10 Degrees C	ISA+15 Degrees C	ISA+20 Degrees C	ISA+25 Degrees C	Above ISA+25 Degrees C
Minimum Engine-Out Cruise Altitude (ft)		18,900	18,800	18,600	18,200	17,900	Prohibited
Maximum Planned Weight at ETOPS Entry Point without Forecast Icing	LBS	474,000	471,600	447,400	416,700	386,000	Prohibited
	KGS	215,000	213,940	202,970	189,040	175,100	
Maximum Planned Weight at ETOPS Entry Point with Forecast Icing	LBS	404,400	394,900	371,700	346,700	321,700	Prohibited
	KGS	183,470	179,120	168,630	157,270	145,910	

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(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

For more information about this AD, contact Tak Kobayashi, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th Street, Des Moines, WA 98198; phone and fax: 206–231–3553; email: *Takahisa.Kobayashi@faa.gov.*

(k) Material Incorporated by Reference

None.

Issued in Des Moines, Washington, on April 12, 2018.

Jeffrey E. Duven,

Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–08127 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 215

[Docket ID: DOD–2017–OS–0056]

RIN 0790–AK07

Employment of Military Resources in the Event of Civil Disturbances

AGENCY: Under Secretary of Defense for Policy, DoD.

ACTION: Final rule.

SUMMARY: This final rule removes the Department of Defense (DoD) regulation regarding employment of military resources in the event of civil disturbances. The part contains uniform DoD policies, assigns responsibilities, and furnishes general guidance for utilizing DoD military and civilian personnel, facilities, equipment, or supplies in support of civil authorities during civil disturbances within the United States. This part is outdated and unnecessary; therefore, it may be removed from the CFR.

DATES: This rule is effective on April 17, 2018.

FOR FURTHER INFORMATION CONTACT: James (Coach) Ross at 571–256–8325.

SUPPLEMENTARY INFORMATION: It has been determined that publication of this CFR part removal for public comment is impracticable, unnecessary, and contrary to public interest since it is based on removing DoD internal policies and procedures that are publicly available on the Department's issuance website.

DoD internal guidance regarding employment of military resources in the event of civil disturbances will continue to be published in DoD Instruction 3025.21, ''Defense Support of Civilian Law Enforcement Agencies,'' available at *http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/302521p.pdf.*

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

List of Subjects in 32 CFR Part 215

Armed forces, Civil disorders, Emergency powers, Intergovernmental relations, Law enforcement, Reporting and recordkeeping requirements, Security measures.

PART 215—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 215 is removed.

Dated: April 12, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–08004 Filed 4–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0326]

Drawbridge Operation Regulation; Willamette River at Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs three Multnomah County bridges: Broadway Bridge, mile 11.7, Morrison Bridge, mile 12.8, and Hawthorne Bridge, mile 13.1 crossing the Willamette River at Portland, OR. This deviation is necessary to accommodate the annual Cinco de Mayo half marathon event. The deviation allows the bridges to remain in the closed-to-navigation position.

DATES: This deviation is effective from 8 a.m. to 9:15 a.m. on May 6, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0326 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

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

SUPPLEMENTARY INFORMATION: Multnomah County, the bridge owner, has requested a temporary deviation from the operating schedule for the Broadway Bridge, mile 11.7, Morrison Bridge, mile 12.8, and Hawthorne Bridge, mile 13.1, all three crossing the Willamette River at Portland, OR. The requested deviation is to accommodate the annual Cinco de Mayo half marathon event. The vertical clearances for theses bridges in the closed-to-navigation position are: Broadway Bridge provides 69 feet, Morrison Bridge provides 69 feet and Hawthorne Bridge provides 49 feet; all clearances are referenced to the vertical clearance above Columbia River Datum 0.0. The normal operating schedule for these bridges is 33 CFR 117.897. This deviation allows the Broadway Bridge, Morrison Bridge, and the Hawthorne Bridge to remain in the closed-to-navigation position, and need not open for maritime traffic from 8 a.m. to 9:15 a.m. on May 6, 2018.

Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft. Vessels able to pass through the subject bridges in the closed-to-navigation position may do so at any time. The bridges will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will inform the users of the waterway, through our Local and Broadcast Notices to Mariners, of the change in operating schedule for the bridges so that vessels can arrange their transits to minimize any impact caused by the temporary deviation. In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedules immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: April 10, 2018.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–07959 Filed 4–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0299]

Drawbridge Operation Regulation; Hood Canal, Port Gamble, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Washington State pontoon highway bridge (Hood Canal Bridge) across Hood Canal, mile 5.0, near Port Gamble, WA. The deviation is necessary to accommodate replacement of the draw span operating equipment. This deviation allows the bridge to open the draw half-way, 300 feet, after receiving at least a four hour notice.

DATES: This deviation is effective from 12:01 a.m. on May 1, 2018, to 11:59 p.m. on September 30, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0299 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

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

SUPPLEMENTARY INFORMATION: The Washington Department of Transportation (WSDOT), the bridge owner, has requested a temporary deviation from the operating schedule of the Hood Canal Bridge. The request is for the subject bridge to be allowed to open half of the draw span to facilitate safe and uninterrupted draw span equipment replacement. The Hood Canal Bridge crosses Hood Canal, mile 5.0, near Port Gamble, WA. The bridge has two fixed spans (east and west), and one draw span (center). The east span provides 50 feet of vertical clearance, the west span provides 35 feet of vertical clearance, and the center span provides zero feet of vertical clearance in the closed-to-navigation position. The center span provides unlimited vertical clearance in the open-to-navigation position. Vertical clearances are referenced to mean high-water elevation.

This deviation allows the center span of the Hood Canal Bridge to open half-way (300 feet vice 600 feet) on signal after receiving at least a four hour notice from 12:01 a.m. on May 1, 2018, to 11:59 p.m. on September 30, 2018. During the period of this deviation, the drawbridge will not be able to operate according to the normal operating schedule. The normal operating schedule for the Hood Canal Bridge is in accordance with 33 CFR 117.1045. The bridge shall operate in accordance to 33 CFR 117.1045 at all other times. Waterway usage on this part of Hood Canal (Admiralty Inlet) includes commercial tugs and barges, U.S. Navy and U.S. Coast Guard vessels, and small pleasure craft. Coordination has been completed with known waterway users, and a no objections to the deviation have been received.

Vessels able to pass through the east and west spans may do so at any time. The center span does not provide passage in the closed-to-navigation position. The subject bridge will be able to open half the center span for Navy and Coast Guard vessels during emergencies, when at least a one hour notice has been given by the Department of the Navy or U.S. Coast Guard. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by this temporary deviation.

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

Dated: April 10, 2018.

Steven Fischer,

Chief, Bridge Program, Thirteenth Coast Guard District.

[FR Doc. 2018–07956 Filed 4–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0327]

Drawbridge Operation Regulation; Lake Washington Ship Canal, Seattle, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Montlake Bridge across Lake Washington Ship Canal, mile 5.2, at Seattle, WA. The deviation is necessary to accommodate the annual Beat the Bridge run to benefit the Juvenile Diabetes Research Foundation. This deviation allows the bridge span to remain in the closed-to-navigation position.

DATES: This deviation is effective from 8 a.m. to 9 a.m. on May 20, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0327 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

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

SUPPLEMENTARY INFORMATION: The Washington Department of Transportation, the bridge owner, has requested a temporary deviation from the operating schedule for the Montlake Bridge across Lake Washington Ship Canal, at mile 5.2, at Seattle, WA. The deviation is necessary to accommodate the safe crossing of event participants. The Montlake Bridge is a double leaf bascule bridge; in the closed-to-navigation position the bridge provides 30 feet of vertical clearance, and provides 46 feet of vertical clearance at the center 60 feet of the bridge. To facilitate this event, the double bascule span is authorized to remain in the closed-to-navigation position from 8 a.m. to 9 a.m. on May 20, 2018. The Coast Guard coordinated with the local mariners by requesting any objections via the Local Notice to Mariners.

The normal operating schedule for the Montlake Bridge operates in accordance with 33 CFR 117.1051(e). Waterway usage on the Lake Washington Ship Canal ranges from commercial tug and barge to small pleasure craft. Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will be able to open for emergencies. Lake Washington Ship Canal has no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: April 10, 2018.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–07957 Filed 4–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0284]

Drawbridge Operation Regulation; Willamette River, Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the upper deck of the Steel Bridge across the Willamette River, mile 12.1, in Portland, OR. The deviation is necessary to support multiple events. This deviation allows the lower lift span of the bridge to remain in the closed-to-navigation position.

DATES: This deviation is effective from 9:30 a.m. on May 6, 2018 to 11:59 p.m. on June 23, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0284, is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

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

SUPPLEMENTARY INFORMATION: Union Pacific Railroad Company (UPRR) owns and operates the Steel Bridge across the Willamette River, at mile 12.1, in Portland, OR. UPRR requested a temporary deviation from the operating schedule for the Steel Bridge upper lift span. The deviation is necessary to accommodate multiple community events. This deviation authorizes UPRR to operate the Steel Bridge upper lift span as follows:

Time/date start	Time/date end	Action
8 a.m./May 6, 2018	9:30 a.m./May 6, 2018	Upper lift closed.
7 p.m./June 2, 2018	11:59 p.m./June 2, 2018	Upper lift closed.
7 a.m./June 9, 2018	1 p.m./June 9, 2018	Upper lift closed.
4 a.m./June 23, 2018	11:59 p.m./June 23, 2018	Upper lift closed.

The Steel Bridge is a double-deck lift bridge, and the lower lift span operates independent of the upper lift span. To facilitate this deviation, the upper deck will remain in the closed-to-navigation position. When the lower deck is in the closed-to-navigation position, the bridge provides 26 feet of vertical clearance above Columbia River Datum 0.0; and in open-to-navigation position, the vertical clearance is 71 feet above Columbia River Datum 0.0. The lower lift deck of the Steel Bridge operates in accordance with 33 CFR 117.5. The upper lift deck of the Steel Bridge operates in accordance with 33 CFR 117.897(c)(3)(ii), and at the end of this deviation period, the upper deck of the Steel Bridge will resume operating in accordance with 33 CFR 117.897(c)(3)(ii).

Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft. Vessels able to pass through the subject bridge with the upper deck in the closed-to-navigation position may do so at any time. The lower lift of the Steel Bridge will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard requested objections be submitted to this deviation in the Local Notice to Mariners. We have not received any objections to this temporary deviation from the operating schedule. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the subject bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: April 10, 2018.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–07955 Filed 4–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0068]

RIN 1625–AA09

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway and Biscayne Bay, Miami, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is modifying the operating schedule that governs the Venetian Causeway Bridge (West) across the Atlantic Intracoastal Waterway mile 1088.6, and the operating schedule that governs the Venetian Causeway Bridge (East) across Biscayne Bay, Miami Beach, FL. This action will extend the daily twice an hour opening schedule of the Venetian Causeway Bridges (East and West) to include weekends and Federal holidays. This action is intended to reduce vehicular traffic caused by the on-demand weekend and Federal holiday bridge openings.

DATES: This rule is effective May 17, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov.* Type USCG–2017–0068 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Ruth Sadowitz, Coast Guard Sector Miami, FL, Waterways Management Division, telephone 305–535–4307, email *ruth.a.sadowitz@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of proposed rulemaking (Advance, Supplemental)
§ Section
U.S.C. United States Code
AICW Atlantic Intracoastal Waterway
FDOT Florida Department of Transportation
FL Florida
MHW Mean High Water

II. Background Information and Regulatory History

On September 5, 2017, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulation; Atlantic Intracoastal Waterway and Biscayne Bay, Miami, FL in the **Federal Register** (82 FR 41901). We received 2 comments on this rule.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 499.

The Venetian Causeway Bridge (West), across the Atlantic Intracoastal Waterway, mile 1088.6, is a double leaf bascule bridge and has a vertical clearance of 12 feet at Mean High Water (MHW) in the closed to navigation position and a horizontal clearance of 90 feet between fenders. The Venetian Causeway Bridge (East), across Biscayne Bay, at Miami Beach, FL is a double leaf bascule bridge with a vertical clearance of 5 feet at MHW in the closed to navigation position and a horizontal clearance of 57 feet between fenders. Presently, in accordance with 33 CFR 117.261(nn) and 33 CFR 117.269, the bridges shall open on signal, except that from 7 a.m. to 7 p.m., Monday through Friday, except Federal holidays, the bridges need only open on the hour and half hour.

Miami-Dade County, the bridge owner, and the Cities of Miami and Miami Beach requested the daily twice an hour operating schedule for both bridges be changed to include weekends and Federal holidays. This should provide relief to the increase vehicle traffic congestion on the weekends while meeting the reasonable needs of navigation.

IV. Discussion of Comments, Changes and the Final Rule

Of the 2 comments received, one was a political statement that had no bearing on the proposed regulation; the second comment was in favor of the operating schedule change. The submitter in favor of the change did suggest that there may be a negative impact to small entities on land economically if the bridge is open for an extended period of time allowing vessels that have been waiting to pass and vice versa for commercial vessels that missed the opening and have to wait until the next scheduled opening. While the Coast Guard does acknowledge that there may be additional vessels waiting for openings due to this change, it should not have a substantial negative impact on land and maritime traffic as it mirrors the current operating schedule Monday through Friday.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the continued ability for vessels to transit the bridge during the twice-an-hour opening schedule. Vessels in distress, Public vessels of the United States and tugs with tows must be passed at any time.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rule. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Government

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

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

we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule simply promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction.

A Record of Environmental Consideration and a Memorandum for the Record are not required for this 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.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

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

■ 2. Amend § 117.261 by revising paragraph (nn) to read as follows:

§ 117.261 Atlantic Intracoastal Waterway from St. Marys River to Key Largo.

* * * * *

(nn) The Venetian Causeway Bridge (West), mile 1088.6, at Miami. The draw shall open on signal, except that from 7 a.m. to 7 p.m. daily, including Federal holidays, the draw need only open on the hour and half hour.

* * * * *

■ 3. Revise § 117.269 to read as follows:

§ 117.269 Biscayne Bay.

The Venetian Causeway Bridge (East), across Miami Beach Channel. The draw shall open on signal, except that from 7 a.m. to 7 p.m. daily, including Federal holidays, the draw need only open on the hour and half hour.

Dated: February 8, 2018.

Peter J. Brown,

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

[FR Doc. 2018–08011 Filed 4–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0205]

RIN 1625–AA00

Safety Zone; Barge PFE–LB444, San Joaquin River, Blackslough Landing, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the San Joaquin River due to an unstable, partially submerged barge with hull number PFE–LB444. The temporary safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the barge and associated recovery efforts. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port San Francisco.

DATES: This rule is effective without actual notice from April 17, 2018 until April 30, 2018. For the purposes of enforcement, actual notice will be used from March 30, 2018 until April 17, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2018–0205 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade Emily K. Rowan, U.S. Coast Guard Sector San Francisco; telephone 415–399–7443, email *emily.k.rowan@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because of the emergent nature of the situation. Delaying the effective date of this rule would be impracticable because immediate action is needed protect personnel, vessels, and the marine environment from potential hazards associated with the barge and associated recovery efforts.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. A barge with hull number PFE–LB444 broke free from its mooring near Blackslough Landing and sank in the navigable channel. This vessel has since been temporarily secured to shore. The barge remains in an unstable condition and continues to shift in orientation and aspect. A safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with the barge and associated recovery efforts.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to establish safety zones. The Captain of the Port San Francisco (COTP) has determined that potential hazards associated with the barge and associated recovery efforts starting March 30, 2018, will be a safety concern for anyone within a 90-yard radius of the barge. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from March 30, 2018 through April 30, 2018. The safety zone will cover all navigable waters within 90 yards of the unstable barge and associated recovery efforts centered in approximate position 37°59′41.88″ N, 121°25′8.88″ W (NAD 83). The effect of the temporary safety zone is intended to protect personnel, vessels, and the marine environment in these navigable waters from potential hazards associated with the barge and associated recovery efforts. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the limited duration and narrowly tailored geographic area of the safety zone. Although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users will be notified via public Broadcast Notice to Mariners to ensure the safety zone will result in minimum impact. The entities most likely to be affected are waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities.

B. Impact on Small Entities

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

This rule may affect the following entities, some of which may be small entities: Owners and operators of waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities and sightseeing, if these facilities or vessels are in the vicinity of the safety zone at times when this zone is being enforced. This rule will not have a significant economic impact on a substantial number of small entities for the following reasons: (i) This rule will encompass only a small portion of the waterway for a limited period of time, and (ii) the maritime public will be advised in advance of these safety zones via Broadcast Notice to Mariners.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves safety zones of limited size and duration. It is categorically excluded from further review under Categorical Exclusion L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination will be prepared and submitted after issuance or publication in accordance with DHS Instruction Manual 023–01–001–01, Rev. 01.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters.

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T11–921 to read as follows:

§ 165.T11–921 Safety Zone; Barge PFE–LB444, San Joaquin River, Blackslough Landing, CA.

(a) *Location.* The following area is a safety zone: all navigable waters within 90 yards of the unstable, partially submerged barge and associated recovery efforts centered in approximate position 37°59′41.88″ N, 121°25′8.88″ W (NAD 83).

(b) *Enforcement period.* The zone described in paragraph (a) of this section will be enforced from March 30, 2018 through April 30, 2018. The Captain of the Port San Francisco (COTP) will notify the maritime community of periods during which these zones will be enforced via Broadcast Notice to Mariners in accordance with 33 CFR 165.7.

(c) *Definitions.* As used in this section, ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer on a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the COTP in the enforcement of the safety zone.

(d) *Regulations.* (1) Under the general regulations in 33 CFR part 165, subpart C, entry into, transiting or anchoring within this safety zone is prohibited unless authorized by the COTP or the COTP's designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or a designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or a designated representative. Persons and vessels may request permission to enter the safety zones on VHF–23A or through the 24-hour Command Center at telephone (415) 399–3547.

Dated: March 29, 2018

Anthony J. Ceraolo,

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

[FR Doc. 2018–08012 Filed 4–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–0159]

RIN 1625–AA00

Safety Zone; Recurring Marine Events, Sector Key West, Florida

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing moving safety zones for certain waters within the Sector Key West Captain of the Port (COTP) Zone for five annually recurring marine events. This action is necessary to provide for the safety of the participants, participant vessels, and the general public on the navigable waters of the United States during these events. When these safety zones are activated and subject to enforcement, this rule would prohibit persons and vessels, other than those participating in the event, from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the COTP Key West or a designated representative.

DATES: This rule is effective May 17, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2017–0159 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rulemaking, call or email Lieutenant Scott Ledee, Waterways Management Division Chief, Sector Key West, FL, U.S. Coast Guard; telephone (305) 292–8768, email *SKWWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

Swim events and marine events are held on an annual recurring basis on the navigable waters within the Sector Key West COTP Zone. In the past, the Coast Guard has established safety zones for these annual recurring events on a case by case basis to ensure the protection of the maritime public and event participants from the hazards associated with these events. This rule will consistently apprise the public in a timely manner through permanent publication in Title 33 of the Code of Federal Regulations. The Table in this rule lists each annual recurring event requiring a regulated area as administered by the Coast Guard.

By establishing a permanent regulation containing these annual recurring marine events, the Coast Guard would eliminate the need to establish temporary rules for events that occur on an annual basis. On May 16, 2017, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; Recurring Marine Events, Sector Key West, Florida, 82 FR 22448. There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to these recurring marine events. During the comment period that ended June 15, 2017, we received no comments.

The legal basis and authorities for this rule is found in 33 U.S.C. 1231.

III. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published May 16, 2017. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM. This rule establishes five new annually recurring marine events to 33 CFR 165.786, as listed in the attached Table to § 165.786. The Table provides the event name, the sponsor name, the location of the event, and the approximate date and time of each event. The specific times, dates, regulated areas and enforcement period

for each event will be provided through Broadcast Notice to Mariners, a Notice of Enforcement published in the **Federal Register**, and the Local Notice to Mariners which can be found at the following link: *https://www.navcen.uscg.gov/?pageName=lnmDistrict&region=7.*

The safety zones established by this rule would cover all waters within 50 yards in front of the lead safety vessel preceding the first event participants, 50 yards behind the safety vessel trailing the last event participants, and at all times extend 100 yards on either side of the safety vessels.

This rule prevents vessels from transiting areas specifically designated as safety zones during the periods of enforcement to ensure the protection of the maritime public and event participants from the hazards associated with the listed annual recurring events. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP Key West or a designated representative.

The regulatory text appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on: (1) The safety zones would only be enforced during limited time intervals during the swim and paddle events; (2) vessels may be authorized to enter the regulated areas with permission of the COTP Key West or a designated representative; and (3) advanced notification of closures will be made via Local Notice to Mariners, Broadcast to Mariners, and through a Notice of Enforcement published in the **Federal Register**.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule 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 rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it 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 rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule 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 rule under Department of Homeland Security Directive 023–01, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of safety zones. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add a new § 165.786 to read as follows:

§ 165.786 Safety Zone; recurring marine events, Sector Key West, Florida.

(a) *Regulations.* (1) In accordance with 33 CFR 165.23, entering, transiting through, anchoring in, or remaining within the safety zones listed in the Table to § 165.786 during periods of enforcement is prohibited unless authorized by the Captain of the Port (COTP) Sector Key West or a designated representative.

(2) These regulations will be enforced for the duration of each event. Notifications of exacts dates and times of the enforcement period will be made to the local maritime community through the Local Notice to Mariners and Broadcast Notice to Mariners and through a Notice of Enforcement in the **Federal Register** well in advance of the events. Mariners should consult the **Federal Register** or their Local Notice to Mariners to remain apprised of schedule their Local Notice to Mariners to remain apprised of schedule or event changes.

(3) During periods of enforcement, upon being hailed by a Coast Guard vessel by siren, radio, flashing light or other means, the operator must proceed as directed.

(4) Vessel operators desiring to enter, transit through, anchor in, or remain within the regulated area during the enforcement period shall contact the COTP Sector Key West or the designated on-scene representative via VHF channel 16 or call the Sector Key West Command Center at (305) 292–8727 to obtain permission.

(b) *Definition.* The term ''designated representative'' means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the COTP Key West in the enforcement of the regulated areas.

(c) The COTP Key West or designated representative may delay or terminate any event in this subpart at any time to ensure safety of life or property. Such action may be justified as a result of weather, traffic density, spectator operation, or participant behavior.

(d) The regulated area for all marine events listed in Table 1 of § 165.786 is that area of navigable waters within 50 yards in front of the lead safety vessel preceding the first event participants, 50 yards behind the safety vessel trailing the last event participants, and at all times extend 100 yards on either side of safety vessels.

TABLE TO § 165.786

[Datum NAD 1983]

4.0	APRIL
4.1 Key West Paddle Board Classic	Event Type: Paddle Event. Sponsor: Lazy Dog Adventure Outfitters. Dates: A one day event held on the last weekend in April. Time (Approximate): 9:00 a.m. to 4:00 p.m., daily. Location(s): Begins at Higgs Beach in Key West, Florida at a point Latitude 24°32.81′ N, longitude 081°47.20′ W, thence west offshore of Fort Zach State Park to latitude 24°32.72′ N, longitude 081°48.77′ W, thence north through Key West Harbor to latitude 24°34.10′ N, longitude 081°48.14′ W, thence east through Fleming Cut to latitude 24°34.42′ N, longitude 081°45.08′ W, south on Cow Key Channel to latitude 24°33.04′ N, longitude 081°44.98′ W, and thence west to point of origin at latitude 24°32.81′ N, longitude 081°47.20′ W.
6.0	**JUNE**
6.1 FKCC Swim Around Key West	Event Type: Swim Event. Sponsor: Florida Keys Community College. Dates: A one day event held on a Saturday in June. Time (Approximate): 7:30 a.m. to 4:00 p.m. Location(s): Begins at Smathers Beach in Key West, Florida at a point Latitude 24°33.01′ N, longitude 081°46.47′ W, thence west offshore of Fort Zach State Park to latitude 24°32.72′ N, longitude 081°48.77′ W, thence north through Key West Harbor to latitude 24°34.10′ N, longitude 081°48.14′ W, thence east through Fleming Cut to latitude 24°34.42′ N, longitude 081°45.08′ W, south on Cow Key Channel to latitude 24°33.04′ N, longitude 081°44.98′ W, and thence west to point of origin at latitude 24°33.01′ N, longitude 081°46.47′ W.
6.2 Annual Swim Around Key West	Event Type: Swim Event. Sponsor: Key West Athletic Association. Dates: A one day event held on a Saturday in June. Time (Approximate): 7:30 a.m. to 4:00 p.m.

TABLE TO § 165.786—Continued

[Datum NAD 1983]

	Location(s): Begins at Smathers Beach in Key West, Florida at a point Latitude 24°33.01′ N, longitude 081°46.47′ W, thence west offshore of Fort Zach State Park to latitude 24°32.72′ N, longitude 081°48.77′ W, thence north through Key West Harbor to latitude 24°34.10′ N, longitude 081°48.14′ W, thence east through Fleming Cut to latitude 24°34.42′ N, longitude 081°45.08′ W, south on Cow Key Channel to latitude 24°33.04′ N, longitude 081°44.98′ W, and thence west to point of origin at latitude 24°33.01′ N, longitude 081°46.47′ W.
7.0	JULY
7.1 Hemingway Paddle Board Race	Event Type: Paddle Event. Sponsor: Hemingway Sunset Run LLC. Dates: A one day event held on the 2nd or 3rd Saturday in July. Time (Approximate): 6:00 p.m. to 7:30 p.m. Location(s): Begins at Higgs Beach in Key West, Florida at a point Latitude 24°32.79′ N, longitude 081°47.74′ W, thence east to latitude 24°32.56′ N, longitude 081°47.11′ W, thence east to latitude 24°33.01′ N, longitude 081°46.47′ W, thence west to latitude 24°32.56′ N, longitude 081°47.11′ W, and thence west to point of origin at latitude 24°32.79′ N, longitude 081°47.74′ W.
9.0	SEPTEMBER
9.1 Swim for Alligator Lighthouse	Event Type: Swim Event. Sponsor: Friends of the Pool. Dates: A one day event held on the 3rd Saturday in September. Time (Approximate): 7:30 a.m. to 4:30 p.m. Location(s) (Primary): Beginning at a point Latitude 24°54.82′ N, longitude 080°38.03′ W, thence to latitude 24°54.36′ N, longitude 080°37.72′ W, thence to latitude 24°51.07′ N, longitude 080°37.14′ W, thence to latitude 24°54.36′ N, longitude 080°37.72′ W, thence to point of origin at latitude 24°54.82′ N, longitude 080°38.03′ W. Location(s) (Alternate)[1]: Beginning at a point Latitude 24°54.82′ N, longitude 080°38.03′ W, thence to latitude 24°53.25′ N, longitude 080°37.04′ W, thence to latitude 24°52.05′ N, longitude 080°38.85′ W, thence to latitude 24°54.36′ N, longitude 080°37.72′ W, thence to point of origin at latitude 24°54.82′ N, longitude 080°38.03′ W.

Dated: April 3, 2018.

Jeffrey A. Janszen,

Captain, U.S. Coast Guard, Captain of the Port Key West.

[FR Doc. 2018–08014 Filed 4–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

[COE–2017–0007]

United States Air Force 81st Security Forces Anti-Terrorism Office, Restricted Area, Keesler Air Force Base, Biloxi, Mississippi

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: The U.S. Army Corps of Engineers (Corps) is establishing a no anchorage restricted area within waters along the Back Bay of Biloxi shoreline of the Keesler Air Force Base (KAFB) located in Biloxi, Mississippi, on behalf of a request by the United States Air Force (USAF) 81st Security Forces Anti-Terrorism Office. The no anchorage restricted area will be established by placing 12 buoys to demarcate the approximately 10,000 feet of shoreline east to west and extend approximately 150 feet from the shoreline of the base. The restricted area is essential to address a major anti-terrorism and safety concern due to the lack of perimeter fencing or physical denial system.

DATES: *Effective Date:* May 17, 2018.

ADDRESSES: U.S. Army Corps of Engineers, Attn: CECW–CO (David Olson), 441 G Street NW, Washington, DC 20314–1000.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202–761–4922 or Mr. Don Mroczko, U.S. Army Corps of Engineers, Mobile District, at 251–690–3185.

SUPPLEMENTARY INFORMATION: The 81st Security Forces Anti-Terrorism Office, KAFB, located in Biloxi, Mississippi is responsible for United States Air Force perimeter security at KAFB located in Biloxi, Mississippi. In accordance with Department of Defense and Department of the Air Force guidance, the 81st Security Forces Anti-Terrorism Office is responsible for the antiterrorism efforts and force protection of Department of the Air Force assets under his or her charge. In response to a request by the United States Air Force, and pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat. 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3), the Corps is amending the regulations in 33 CFR part 334 by establishing a new restricted area.

The proposed rule was published in the November 16, 2017, edition of the **Federal Register** (82 FR 53440) and the docket number was COE–2017–0007. In response to the proposal, four comments were received. One commenter stated support for the project. Three agency

comments were received stating no objections to the proposal regarding cultural resources and fish and wildlife habitat.

In response to a request by the United States Air Force, and pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat. 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3), the Corps is amending the regulations in 33 CFR part 334 by establishing a new restricted area.

Procedural Requirements

a. *Regulatory Planning and Review.*

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

The Corps has made a determination this rule is not a significant regulatory action. This regulatory action determination is based on the size, duration, and location of the restricted area. The restricted area occupies a small portion of the waterway and a vessel that needs to transit the restricted area may do so if the operator of the vessel obtains permission from the USAF 81st Security Forces Anti-Terrorism Office, KAFB or its authorized representative.

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 Corps certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities. While some owners or operators of vessels that intend to transit the restricted area may be small entities, for the reasons stated in paragraph (a) above this rule would not have a significant economic impact on any vessel owner or operator. In addition, the restricted area is necessary to address a major anti-terrorism and safety concern due to the lack of perimeter fencing or physical denial system. Small entities can utilize navigable waters outside of the restricted area. Small entities may also transit the restricted area as long as they obtain permission from the USAF 81st Security Forces Anti-Terrorism Office, KAFB, Biloxi, Mississippi, or its authorized representative. The restricted area is necessary for security of KAFB. The Corps determined that the restricted area would have practically no economic impact on the public, any anticipated navigational hazard or interference with existing waterway traffic. After considering the economic impacts of this restricted area regulation on small entities, I certify that this action will not have a significant impact on a substantial number of small entities.

c. *Review Under the National Environmental Policy Act.* This rule will not have a significant impact to the quality of the human environment and, therefore, preparation of an environmental impact statement is not required. An environmental assessment has been prepared. It may be reviewed at the District office listed at the end of the **FOR FURTHER INFORMATION CONTACT** section, above.

d. *Unfunded Mandates Act.* This rule does not impose an enforceable duty among the private sector and, therefore, is not a Federal private sector mandate and is not subject to the requirements of Section 202 or 205 of the Unfunded Mandates Reform Act (Pub. L. 104–4, 109 Stat. 48, 2 U.S.C. 1501 *et seq.*). We have also found under Section 203 of the Act, that small governments will not be significantly or uniquely affected by this rule.

List of Subjects in 33 CFR Part 334

Danger zones, Navigation (water), Restricted areas, Waterways.

For the reasons set out in the preamble, the Corps amends 33 CFR part 334 as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

■ 1. The authority citation for part 334 continues to read as follows:

Authority: 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3).

■ 2. Add § 334.787 to read as follows:

§ 334.787 81st Security Forces Anti-Terrorism Office, Keesler Air Force Base, Biloxi, Mississippi; no anchorage restricted area.

(a) *The area.* The restricted area shall encompass all navigable waters of the United States, as defined at 33 CFR part 329, contiguous to the area identified as Keesler Air Force Base (KAFB) and the mean high water level within an area bounded by the shore and buoys from the east to the west of the area starting at: Latitude 30°25′11.73″ N, longitude 88°54′57.69″ W, thence to latitude 30°25′11.85″ N, longitude 88°55′3.46″ W, thence to latitude 30°25′8.00″ N, longitude 88°55′10.10″ W, thence to latitude 30°25′4.15″ N, longitude 88°55′16.74″ W, thence to latitude 30°25′6.96″ N, longitude 88°55′24.12″ W, thence to latitude 30°25′1.83″ N, longitude 88°55′30.01″ W, thence to latitude 30°24′56.15″ N, longitude 88°55′34.16″ W, thence to latitude 30°24′51.14″ N, longitude 88°55′39.56″ W, thence to latitude 30°24′47.48″ N, longitude 88°55′46.64″ W, thence to latitude 30°24′51.08″ N, longitude 88°55′53.46″ W, thence to latitude 30°24′55.30″ N, longitude 88°55′59.91″ W, thence to latitude 30°24′56.87″ N, longitude 88°56′7.40″ W. The datum is NAD–83.

(b) *The regulations.* (1) All persons, swimmers, vessels and other craft, except those vessels under the supervision or contract to local military or USAF authority, vessels of the United States Coast Guard, and local or state law enforcement vessels, are prohibited from entering the restricted area without permission from the USAF 81st Security Forces Anti-Terrorism Office, KAFB or its authorized representative.

(2) The restricted area is in effect twenty-four hours per day and seven days a week (24/7).

(3) Should warranted access into the restricted navigation area be needed, all entities are required to contact the USAF 81st Security Forces Anti-Terrorism Office, KAFB, Biloxi, Mississippi, or its authorized representative.

(c) *Enforcement.* The regulation in this section shall be enforced by the USAF 81st Security Forces Anti-Terrorism Office, KAFB and/or such agencies or persons as that office may designate.

Dated: April 6, 2018.

Thomas P. Smith,

Chief, Operations and Regulatory Division, Directorate of Civil Works.

[FR Doc. 2018–07919 Filed 4–16–18; 8:45 am]

BILLING CODE 3720–58–P

LEGAL SERVICES CORPORATION

45 CFR Part 1603

State Advisory Councils

AGENCY: Legal Services Corporation.

ACTION: Final rule.

SUMMARY: This final rule removes the Legal Services Corporation (LSC) regulation on state advisory councils. LSC believes this action is appropriate because the state advisory councils are no longer active and their oversight functions have been replaced adequately by other offices and processes established since the regulation was promulgated. Executive Orders 13563, ''Improving Regulation and Regulatory Review,'' and 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' direct agencies to review their existing regulations and repeal or revise any that are obsolete or unnecessarily burdensome. Although LSC is not an agency of the Federal government subject to either Executive order, LSC regularly reviews its regulations and has determined that this regulation can be eliminated.

DATES: This final rule is effective on May 17, 2018.

FOR FURTHER INFORMATION CONTACT: Stefanie K. Davis, Assistant General Counsel, Legal Services Corporation, 3333 K Street NW, Washington, DC 20007; (202) 295–1563 (phone), (202) 337–6519 (fax), or *sdavis@lsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 1004(f) of the Legal Services Corporation Act of 1974 required that ''within six months after the first meeting of the Board, the Board request the Governor of each State to appoint a nine-member advisory council for each state.'' 42 U.S.C. 2996c(f). If ninety days elapsed without the Governor's appointing the advisory council, then ''the Board [was] authorized to appoint such a council.'' *Id.* LSC implemented this statutory requirement in 1975 at 45 CFR part 1603.

The state advisory councils' primary duty was to notify LSC of any ''apparent violation'' by a recipient. 45 CFR 1603.5. LSC defined ''apparent violation'' as ''a complaint or other written communication alleging facts which, if established, constitute a violation of the [LSC] Act, or any applicable rules, regulations or guidelines promulgated pursuant to the Act.'' *Id.* § 1603.2(b).

LSC met the requirements of § 1004(f) of the LSC Act by requesting state governors to appoint state advisory councils within the period established by the Act and part 1603. In 1976, 46 state advisory councils were in existence, but later reports reflect that many of these councils rarely, if ever, met. Letter from Suzanne B. Glasow, Senior Counsel for Operations and Regulations, Office of General Counsel, to Mike Sims, Office of Rep. Pete Laney at 1 (Sept. 19, 1989). By 1983, only six state advisory councils appeared to be operational and by 1989, only Colorado and Indiana had functioning state advisory councils. *Id.* After a diligent search of its records, LSC concluded that there currently are no active state advisory councils and that LSC has no records of complaints forwarded from the state advisory councils.

II. History of This Rulemaking

In 2014, LSC's Office of the Inspector General (OIG) recommended that LSC either ensure that the state advisory councils have been established and are operational or rescind part 1603. LSC is rescinding part 1603 for four reasons: (1) LSC complied with the requirements of section 1004(f) of the LSC Act by requesting state governors to appoint state advisory councils within the period established by the Act and part 1603; (2) section 1004(f) of the LSC Act and part 1603 provide LSC with discretion to exercise or not exercise the option to appoint state councils; (3) to LSC's knowledge, there are no functioning state advisory councils; and (4) there are now numerous oversight mechanisms that fulfill the function of the state advisory councils.

At its January 2015 meeting, the Operations and Regulations Committee (Committee) of LSC's Board of Directors (Board) recommended including the repeal of part 1603 on LSC's regulatory agenda, but made the initiative a low priority.

On January 30, 2017, the President signed Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs.'' Through this Executive order, the President directed the heads of executive departments and agencies to identify at least two prior regulations to be repealed for each new regulation issued. By operation of the LSC Act, LSC is not an executive department or agency subject to the Executive order. 42 U.S.C 2996d(e). Consistent with the intent of the Executive order to reduce unnecessary regulations, however, LSC prioritized the repeal of part 1603.

Prior to initiating rulemaking, LSC conducted an analysis of the oversight mechanisms that have developed since the LSC Act was passed in 1974. LSC determined that the state advisory councils' oversight functions have been replaced adequately by other offices and processes established since 1974. Complainants not only have more audiences—including LSC's OIG, LSC's Office of Compliance and Enforcement (OCE), and state bodies—for their complaints, but they also have more vehicles for filing complaints, including by phone, postal mail, email, online, and through grantee grievance procedures. The OIG and OCE go beyond the state advisory committees' narrow role of collecting alleged violations by also investigating the allegations and using various tools to ensure grantee compliance. Furthermore, state and local funding, state access to justice commissions, and the role of state and local bars in appointing grantee board members all ensure that there is continued local involvement in legal aid funded by LSC. LSC's analysis of these mechanisms is covered in greater detail in the Justification Memorandum for Rulemaking to Rescind 45 CFR part 1603—State Advisory Councils (Justification Memo), *available at www.lsc.gov/rulemaking.*

On April 23, 2017, the Committee approved Management's proposed 2017–2018 rulemaking agenda, which included rescinding 45 CFR part 1603 as a priority rulemaking item. On October 15, 2017, the Committee voted to recommend that the Board authorize LSC to begin rulemaking on part 1603. On October 17, 2017, the Board authorized LSC to begin rulemaking. On January 21, 2018, the Committee voted to recommend that the Board authorize publication of a Notice of Proposed Rulemaking (NPRM) proposing to repeal part 1603. On January 23, 2018, the Board authorized publication of the NPRM with a 30-day comment period. On February 1, 2018, LSC published the NPRM in the **Federal Register**, 83 FR 4826.

On April 8, 2018, the Committee voted to recommend that the Board adopt this final rule and approve its publication in the **Federal Register**. On April 10, 2018, the Board voted to adopt and publish this final rule.

III. Discussion of the Comment

During the 30-day public comment period, LSC received one comment from a current law student. The commenter generally supported LSC's proposal to remove part 1603, citing reasons similar to those presented by LSC in the Justification Memo and NPRM. The commenter suggested that the councils could be re-established to ensure continued local involvement. LSC's Justification Memo addressed this

concern directly by describing the variety of mechanisms—for example, state Access to Justice Commissions and recipients' own grievance procedures—that ensure local involvement in the operations of LSC funding recipients.

The comment also stated that the ''[t]he decision [whether to repeal] should be based on what affect[s] the United States taxpayers.'' LSC agrees. LSC does not think it would be a good use of LSC resources, which include taxpayer money, to rejuvenate the state advisory councils when their functions are being performed well by a variety of other mechanisms, as highlighted in the Justification Memo and the NPRM.

IV. Discussion of the Final Rule

LSC is removing part 1603. In a final rule published elsewhere in this issue of the **Federal Register**, LSC is adding to part 1603 a regulation governing requests for testimony and subpoenas for documents in cases to which LSC is not a party.

Materials regarding this rulemaking are available in the open rulemaking section of LSC's website at *http://www.lsc.gov/about-lsc/laws-regulations-guidance/rulemaking.* After the effective date of the rule, those materials will appear in the closed rulemaking section at *http://www.lsc.gov/about-lsc/laws-regulations-guidance/rulemaking/closed-rulemaking.*

List of Subjects in 45 CFR Part 1603

Advisory committees; Legal services.

PART 1603—[REMOVED]

■ For the reasons discussed in the preamble and under the authority of 42 U.S.C. 2996g(e), LSC is removing 45 CFR part 1603.

Dated: April 11, 2018.

Stefanie Davis,

Assistant General Counsel.

[FR Doc. 2018–07963 Filed 4–16–18; 8:45 am]

BILLING CODE 7050–01–P

SURFACE TRANSPORTATION BOARD

49 CFR Parts 1001, 1003, 1004, 1005, 1007, 1011, 1012, 1013, 1016, 1018, 1019, 1033, 1034, 1035, 1037, 1090, 1100, 1101, 1103, 1104, 1105, 1106, 1108, 1110, 1112, 1113, 1114, 1116, 1117, 1119, 1120, 1132, 1133, 1135, 1141, 1144, 1146, 1147, 1150, 1152, 1155, 1177, 1180, 1182, 1184, 1185, 1200, 1220, 1242, 1243, 1244, 1245, 1246, 1247, 1248, 1253, 1305, 1310, 1312, 1313, 1319, 1331, and 1333

[Docket No. EP 746]

Updating the Code of Federal Regulations

Correction

In rule document 2018–06657 beginning on page 15075 in the issue of Monday, April 9, 2018, make the following correction:

On page 15080, in the first column, amendatory instruction 70 should read as follows:

■ ''70. In § 1182.2(a)(11), remove ''21 U.S.C. 853a'' and add in its place ''21 U.S.C. 862''. ''

[FR Doc. C1–2018–06657 Filed 4–16–18; 8:45 am]

BILLING CODE 1301–00–D

Proposed Rules

Federal Register
Vol. 83, No. 74
Tuesday, April 17, 2018

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0277; Product Identifier 2017–NM–124–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2017–15–17, which applies to certain Airbus Model A300 B4–600R series airplanes, Model A300 C4–605R Variant F airplanes, and Model A300 F4–600R series airplanes. AD 2017–15–17 requires an inspection of the lower area of a certain frame radius for cracking, and corrective action if necessary. Since we issued AD 2017–15–17, we have determined that repetitive inspections and applicable corrective actions are necessary. This proposed AD would add new repetitive inspections of the lower area of a certain frame radius for cracking, and corrective actions if necessary. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by June 1, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0277; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0277; Product Identifier 2017–NM–124–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We issued AD 2017–15–17, Amendment 39–18977 (82 FR 35644, August 1, 2017) (''AD 2017–15–17''), for certain Airbus Model A300 B4–600R series airplanes, Model A300 C4–605R Variant F airplanes, and Model A300 F4–600R series airplanes. AD 2017–15–17 was prompted by the detection of cracking that originated from the fastener holes in the forward fitting lower radius of frame (FR) 40. AD 2017–15–17 requires an inspection of the lower area of a certain frame radius for cracking, and corrective action if necessary. We issued AD 2017–15–17 to detect and correct cracking in the forward fitting lower radius of FR 40. Such cracking could reduce the structural integrity of the fuselage.

Since we issued AD 2017–15–17, we have determined that new repetitive inspections of the lower area of a certain frame radius for cracking, and corrective actions are necessary.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2017–0158, dated August 25, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus Model A300 B4–600R series airplanes, Model A300 C4–605R Variant F airplanes, and Model A300 F4–600R series airplanes. The MCAI states:

> Following a full stress analysis of the Frame (FR) 40 lower area, supported by a Finite Element Model (FEM), of the post-mod [modification] 10221 configuration, it was demonstrated that, for the FR40 forward fitting lower radius, a crack could occur after a certain number of flight cycles (FC).
>
> This condition, if not detected and corrected, could reduce the structural integrity of the fuselage.
>
> To address this potential unsafe condition, Airbus established that crack detection could be achieved through a special detailed inspection (SDI) using a high frequency eddy current (HFEC) method, and issued Alert Operators Transmission (AOT) A57W009–16 to provide those inspection instructions.
>
> Consequently, EASA issued AD 2016–0085 to require a one-time SDI of the FR40 lower area and, depending on findings, accomplishment of applicable corrective action(s). After that [EASA] AD was issued, further cracks were detected, originating from

the fastener hole, and, based on these findings, it was determined that the inspection area must be enlarged, and Airbus issued AOT A57W009–16 Revision (Rev.) 01 accordingly. Consequently, EASA issued AD 2016–0179 [which corresponds to FAA AD 2017–15–17], retaining the requirements of EASA AD 2016–0085, which was superseded, to extend the area of inspection, and to require an additional inspection for aeroplanes that were previously inspected.

The one-time SDI for high cycle A300–600 aeroplanes was intended to mitigate the highest risks within the fleet, pending development of instructions for repetitive inspections.

Since EASA AD 2016–0179 was issued, Airbus published SB A300–57–6120 * * * [for] the inspection programme for A300–600 * * * post-mod 10221 * * * [airplanes]. The AOT one-time inspection is superseded by these repetitive inspection SBs. These SBs include alternative inspection methods and repair solutions in case of findings together with the associated inspection programme.

For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2016–0179, which is superseded, * * * and defines new inspections methods with new compliance times, including repetitive inspections, depending on the aeroplane inspection status.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0277.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A300–57–6120, including Appendices 1 through 7, dated April 28, 2017. This service information describes procedures for repetitive inspections of the forward fitting lower radius of FR 40 for cracking, and corrective action. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD affects 94 airplanes of U.S. registry.

The actions required by AD 2017–15–17, and retained in this proposed AD, take about 4 work-hours per product, at an average labor rate of $85 per work-hour. Based on these figures, the estimated cost of the actions that are required by AD 2017–15–17 is $340 per product.

We also estimate that it would take about 4 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $31,960, or $340 per product.

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

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW, Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2017–15–17, Amendment 39–18977 (82

FR 35644, August 1, 2017), and adding the following new AD:

Airbus: Docket No. FAA–2018–0277; Product Identifier 2017–NM–124–AD.

(a) Comments Due Date

We must receive comments by June 1, 2018.

(b) Affected ADs

This AD replaces AD 2017–15–17, Amendment 39–18977 (82 FR 35644, August 1, 2017) (''AD 2017–15–17'').

(c) Applicability

This AD applies to Airbus airplanes, certificated in any category, identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, on which Airbus Modification 10221 was embodied in production.

(1) Airbus Model A300 B4–605R and B4–622R airplanes.

(2) Airbus Model A300 C4–605R Variant F airplanes.

(3) Airbus Model A300 F4–605R and F4–622R airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by the detection of cracking that originated from the fastener holes in the forward fitting lower radius of frame (FR) 40. We are issuing this AD to detect and correct cracking in the forward fitting lower radius of FR 40. Such cracking could reduce the structural integrity of the fuselage.

(f) Compliance

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

(g) Definitions

(1) For the purpose of this AD, the average flight time (AFT) can be established by dividing the flight hours (FHs) by the flight cycles (FCs) counted:

(i) From first flight, for selecting the inspection threshold of the non-repaired area,

(ii) From repair, for selecting the inspection threshold of the repaired area,

(iii) From the last inspection, for selecting the inspection interval.

(2) For the purpose of this AD, Group 1 airplanes are those airplanes already inspected in accordance with paragraph 4.2.2 in Alert Operators Transmission (AOT) A57W009–16, Revision 01, dated July 13, 2016, before the effective date of this AD. Group 2 airplanes are those airplanes not inspected in accordance with paragraph 4.2.2 in AOT A57W009–16, Revision 01, dated July 13, 2016, as of the effective date of this AD.

(3) For the purpose of this AD, inspection method A is a high frequency (HFEC) inspection of the radius and fastener area. Inspection method B is a HFEC inspection of the radius and fastener area and a rototest of the fastener hole. Both are defined as a special detailed inspection (SDI) in this AD.

(h) Repetitive Inspections for Non-Repaired Areas

Within the compliance time specified in table 1 to paragraph (h) of this AD (Group 1 airplanes) or table 2 to paragraph (h) of this AD (Group 2 airplanes), as applicable, and, thereafter, at intervals not exceeding the values specified in table 3 to paragraph (h) of this AD, do a SDI for cracking of any non-repaired radius, fastener areas, and fastener holes, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6120, including Appendices 1 through 7, dated April 28, 2017; except where Airbus Service Bulletin A300–57–6120, including Appendices 1 through 7, dated April 28, 2017, specifies contacting Airbus for appropriate action, before further flight, obtain instructions using the procedures specified in paragraph (l) of this AD and accomplish those instructions.

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Table 1 to Paragraph (h) of this AD – *Group 1 Inspection Thresholds – Non-repaired Areas*

AFT	**Compliance Time** (whichever occurs later, A or B)
Greater than 1.5	**A:** Before exceeding 14,700 FC or 31,900 FH since first flight of the airplane, whichever occurs first. **B**: Within 1,900 FC or 4,300 FH, whichever occurs first after the one-time inspection performed as per AOT A57W009-16 Revision 01, dated July 13, 2016.
1.5 or less	**A:** Before exceeding 15,900 FC or 23,900 FH since first flight of the airplane, whichever occurs first. **B**: Within 2,100 FC or 3,200 FH, whichever occurs first after the one-time inspection performed as per AOT A57W009-16 Revision 01, dated July13, 2016.

Table 2 to Paragraph (h) of this AD – *Group 2 Inspection Thresholds – Non-repaired Areas*

AFT	**Compliance Time** (whichever occurs later, A or B)
Greater than 1.5	**A:** Before exceeding 14,700 FC or 31,900 FH since first flight of the airplane, whichever occurs first. **B**: Within 12 months after the effective date of this AD, without exceeding (whichever occurs later): - 19,000 FC or 41,000 FH, whichever occurs first since airplane first flight. - 300 FC or 630 FH, whichever occurs first after September 5, 2017 (the effective date of AD 2017-15-17).
1.5 or less	**A:** Before exceeding 15,900 FC or 23,900 FH since first flight of the airplane, whichever occurs first. **B**: Within 12 months after the effective date of this AD, without exceeding (whichever occurs later): - 19,000 FC or 41,000 FH, whichever occurs first since airplane first flight. - 300 FC or 630 FH, whichever occurs first after September 5, 2017 (the effective date of AD 2017-15-17).

Table 3 to Paragraph (h) of this AD – *Repetitive Inspections – Non-repaired Areas*

Inspection Method	Compliance Time (not to exceed, whichever occurs first, FC or FH)	
	AFT greater than 1.5	AFT 1.5 or less
A	1,900 FC or 4,300 FH	2,100 FC or 3,200 FH
B	6,600 FC or 14,300 FH	7,100 FC or 10,700 FH

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(i) Repetitive Inspections for Repaired Areas

Within the compliance time values as specified in table 4 to paragraph (i) of this AD, and, thereafter, at intervals not exceeding those same values, do a SDI for cracking of the repaired radius, fastener areas, and fastener holes, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6120, including Appendices 1 through 7, dated April 28, 2017; except where Airbus Service Bulletin A300–57–6120, including Appendices 1 through 7, dated April 28, 2017, specifies contacting Airbus for appropriate action, before further flight, obtain instructions using the procedures specified in paragraph (l) of this AD and accomplish those instructions.

Table 4 to Paragraph (i) of this AD – *Inspection Thresholds and Intervals – Repaired Areas*

Repair (Number)	Compliance Time (FC or FH, whichever occurs first after repair embodiment, or since last inspection, as applicable)	
	AFT greater than 1.5	AFT 1.5 or less
Stop Drilling (R53810799)	1,500 FC or 3,400 FH	1,700 FC or 2,500 FH
Cut-Out (R53810798)	4,500 FC or 9,800 FH	4,900 FC or 7,300 FH

(j) Corrective Action

If any crack is found during any inspection required by paragraph (h) or (i) of this AD: Before further flight, repair in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–6120, including Appendices 1 through 7, dated April 28, 2017.

(k) Reporting

Submit a report of the findings (both positive and negative) of each inspection required by paragraph (h) and (i) of this AD to Airbus, in accordance with the instructions of Airbus Service Bulletin A300–57–6120, including Appendices 1 through 7, dated April 28, 2017, at the applicable time specified in paragraph (k)(1) or (k)(2) of this AD.

(1) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(2) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(l) Other FAA AD Provisions

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (m)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraphs (g) and (h) of this AD: If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2017–0158, dated August 25, 2017, for related information. This MCAI may be found in the AD docket

on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0277.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on March 30, 2018.

Chris Spangenberg,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–07626 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0271; Product Identifier 2017–NM–111–AD]

RIN 2120–AA64

Airworthiness Directives; Saab AB, Saab Aeronautics (Formerly Known as Saab AB, Saab Aerosystems) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2016–13–06, which applies to certain Saab AB, Saab Aeronautics Model 340A (SAAB/SF340A) and SAAB 340B airplanes. AD 2016–13–06 requires a revision of the applicable airplane flight manual (AFM), repetitive inspections of the horizontal stabilizer de-icing boots, and applicable corrective actions. Since we issued AD 2016–13–06, the manufacturer has developed an improved de-icing boot. This proposed AD would continue to require a revision of the applicable AFM, repetitive inspections of the horizontal stabilizer de-icing boots, and applicable corrective actions. This proposed AD would also require replacement of single stitched de-icing boots with improved double stitched boots, and re-identification of the modified horizontal stabilizer leading edge. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by June 1, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Saab AB, Saab Aeronautics, SE–581 88, Linköping, Sweden; telephone: +46 13 18 5591; fax: +46 13 18 4874; email: *saab340techsupport@saabgroup.com;* internet: *http://www.saabgroup.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0271; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0271; Product Identifier 2017–NM–111–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We issued AD 2016–13–06, Amendment 39–18570 (81 FR 41432, June 27, 2016) (''AD 2016–13–06''), for certain Saab AB, Saab Aeronautics Model 340A (SAAB/SF340A) and SAAB 340B airplanes. AD 2016–13–06 was prompted by reports of ruptured horizontal stabilizer de-icing boots. AD 2016–13–06 requires a revision of the applicable AFM, repetitive inspections of the horizontal stabilizer de-icing boots, and applicable corrective actions. We issued AD 2016–13–06 to detect and correct damage of the de-icing boot; such damage could lead to a ruptured boot, severe vibrations, and possible reduced control of the airplane.

Since we issued AD 2016–13–06, the manufacturer has developed an improved de-icing boot, reinforced through double stitch lines.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2017–0144, dated August 9, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Saab AB, Saab Aeronautics Model 340A (SAAB/SF340A) and SAAB 340B airplanes. The MCAI states:

> Several occurrences were reported of rupture of the horizontal stabilizer de-icing boot in flight. In some of the reported events, the de-icing boot had formed a large open scoop.
>
> This condition, if not detected and corrected, could lead to complete loss of the de-icing function within its associated zone and severe vibrations, possibly resulting in reduced control of the aeroplane.
>
> To address this potential unsafe condition, Saab AB, Aeronautics (hereafter referred to as ''Saab'' in this [EASA] AD) issued Alert Operations Bulletin (AOB) No. 12 and AOB No. 23 as temporary measures, recommending to select Flaps 0 for landing in the event of a suspected rupture of the de-icing boot on the horizontal stabilizer. In addition, Saab issued SB [Service Bulletin] 340–30–094 providing instructions for inspection of de-icing boots.

Consequently, EASA issued AD 2015–0129 [which corresponds to FAA AD 2016–13–06] to require amendment of the applicable Aircraft Flight Manual (AFM), repetitive inspections of the horizontal stabilizer de-icing boots and, depending on findings, accomplishment of applicable corrective action(s).

Since that [EASA] AD was issued, Saab developed an improved de-icing boot, reinforced through double stitch lines, and issued SB 340–30–095 providing instructions for boot replacement.

For the reason described above, this [EASA] AD retains the requirements of EASA AD 2015–0129, which is superseded, and requires replacement of single stitched de-icing boots, installed on the left-hand (LH) and right-hand (RH) horizontal stabilizer, with improved double stitched boots, and re-identification of the modified horizontal stabilizer leading edge.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0271.

Related Service Information Under 1 CFR Part 51

Saab AB, Saab Aeronautics has issued the following service information.

- Service Bulletin 340–30–094, dated March 27, 2015. This service information describes procedures for repetitive detailed inspections of the de-icing boots installed on the horizontal stabilizers, and repair and replacement of damaged de-icing boots.
- Service Bulletin 340–30–095, dated April 3, 2017. This service information describes procedures for replacement of single stitched de-icing boots with improved double stitched boots, and re-identification of the modified horizontal stabilizer leading edge.

Saab AB, Saab Aeronautics has also issued the following AFMs, which describe performance limitations and general data. These AFMs are distinct since they apply to different airplane models in different configurations.

- AFM 340A 001, Revision 57, dated March 27, 2015.
- AFM 340B 001, Revision 35, dated March 27, 2015.
- AFM 340B 010, Revision 28, dated March 27, 2015.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Costs of Compliance

We estimate that this proposed AD affects 51 airplanes of U.S. registry.

The actions required by AD 2016–13–06, and retained in this proposed AD take about 6 work-hours per product, at an average labor rate of $85 per work-hour. Based on these figures, the estimated cost of the actions that are required by AD 2016–13–06 is $510 per product.

In addition, we estimate that any necessary follow-on actions required by AD 2016–13–06, and retained in this proposed AD take about 6 work-hours and require parts costing $9,500, for a cost of $10,010 per product. We have no way of determining the number of aircraft that might need these actions.

We also estimate that it would take about 6 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $13,500 per product. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $714,510, or $14,010 per product.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2016–13–06, Amendment 39–18570 (81 FR 41432, June 27, 2016), and adding the following new AD:

Saab AB, Saab Aeronautics (Formerly Known as Saab AB, Saab Aerosystems): Docket No. FAA–2018–0271; Product Identifier 2017–NM–111–AD.

(a) Comments Due Date

We must receive comments by June 1, 2018.

(b) Affected ADs

This AD replaces AD 2016–13–06, Amendment 39–18570 (81 FR 41432, June 27, 2016) (''AD 2016–13–06'').

(c) Applicability

This AD applies to Saab AB, Saab Aeronautics (formerly known as Saab AB, Saab Aerosystems) airplanes, certificated in any category, identified in paragraphs (c)(1) and (c)(2), of this AD.

(1) Saab AB, Saab Aeronautics Model 340A (SAAB/SF340A) airplanes, serial numbers 004 through 138 inclusive, if Saab modification 1462 has been embodied in production, or Saab Service Bulletin 340–55–008 has been embodied in service, except those that have also embodied Saab modification 1793 in production, or Saab Service Bulletin 340–55–010 in service; and serial numbers 139 through 159 inclusive.

(2) Saab AB, Saab Aeronautics Model SAAB 340B airplanes, serial numbers 160 through 459 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 30, Ice and rain protection.

(e) Reason

This AD was prompted by reports of ruptured horizontal stabilizer de-icing boots. We are issuing this AD to detect and correct ruptured horizontal stabilizer de-icing boots, which could lead to complete loss of the de-icing function within its associated zone and severe vibrations, possibly resulting in reduced control of the airplane.

(f) Compliance

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

(g) Retained Revision of the Airplane Flight Manual (AFM), With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2016–13–06, with no changes. Within 30 days after August 1, 2016 (the effective date of AD 2016–13–06), revise the ''Abnormal Procedures'' section of the applicable Saab 340 AFM to incorporate the revision specified in paragraphs (g)(1) through (g)(3) of this AD.

(1) For Saab AB, Saab Aeronautics Model 340A (SAAB/SF340A) airplanes, revise AFM 340A 001 by incorporating Revision 57, dated March 27, 2015.

(2) For Saab AB, Saab Aeronautics Model SAAB 340B airplanes, revise AFM 340B 001 by incorporating Revision 35, dated March 27, 2015.

(3) For Saab AB, Saab Aeronautics Model SAAB 340B airplanes with extended wing tips, revise AFM 340B 010 by incorporating Revision 28, dated March 27, 2015.

(h) Retained Inspection/Replacement, With No Changes

This paragraph restates the requirements of paragraph (h) of AD 2016–13–06, with no changes. Within 400 flight hours or 6 months, whichever occurs first after August 1, 2016 (the effective date of AD 2016–13–06), do a detailed inspection for damage of the horizontal stabilizer de-icing boots, and existing repairs of horizontal stabilizer de-icing boots, in accordance with the Accomplishment Instructions of Saab Service Bulletin 340–30–094, dated March 27, 2015. Repeat the inspection thereafter at intervals not to exceed 400 flight hours. If, during any inspection required by this paragraph, any damage or existing repair outside the limits specified in Saab Service Bulletin 340–30–094, dated March 27, 2015, is found, before further flight, repair or replace the horizontal stabilizer de-icing boots, in accordance with the Accomplishment Instructions of Saab Service Bulletin 340–30–094, dated March 27, 2015. Repair or replacement on an airplane of the horizontal stabilizer de-icing boots, as required by this paragraph, does not constitute terminating action for the repetitive inspections required by this paragraph for that airplane.

(i) New Requirement of This AD: Modification

Within 18 months after the effective date of this AD, modify the airplane by replacing the single stitched de-icing boots installed on the left-hand (LH) and right-hand (RH) horizontal stabilizers with double stitched de-icing boots and re-identify the LH and RH horizontal stabilizer leading edge, in accordance with the Accomplishment Instructions of Saab Service Bulletin 340–30–095, dated April 3, 2017.

(j) Terminating Action

Modification of the airplane as required by paragraph (i) of this AD, constitutes terminating action for the repetitive inspections required by paragraph (h) of this AD, for that airplane.

(k) Other FAA AD Provisions

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (l)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Saab AB, Saab Aeronautics EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2017–0144, dated August 9, 2017, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0271.

(2) For more information about this AD, contact Shahram Daneshmandi, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206–231–3220.

(3) For service information identified in this AD, contact Saab AB, Saab Aeronautics, SE–581 88, Linköping, Sweden; telephone: +46 13 18 5591; fax: +46 13 18 4874; email: *saab340techsupport@saabgroup.com;* internet: *http://www.saabgroup.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on March 30, 2018.

Chris Spangenberg,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–07636 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0142; Product Identifier 2018–NE–04–AD]

RIN 2120–AA64

Airworthiness Directives; General Electric Company CF34–8E Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all General Electric Company (GE) CF34–8E turbofan engines. This proposed AD was prompted by a report from GE regarding a quality escape of nonconforming thrust reverser fire seals. This proposed AD would require a one-time inspection of the gap between the core cowl seal and the pylon seal of the thrust reverser for correct gap width, and replacement of the seals, if needed. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by June 1, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

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

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

For service information identified in this NPRM, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; telephone 513–552–3272; email *aviation.fleetsupport@ge.com.* You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0142; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: David Bethka, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7129; fax: 781–238–7199; email: *david.bethka@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0142; Product Identifier 2018–NE–04–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

We received a report from the manufacturer about a fire seal gap quality escape on GE CF34–8E turbofan engines. Some thrust reverser fire seals, installed on thrust reverser part numbers (P/Ns) 15G0002–013, 15G0002–014, 15G0003–013, and 15G0003–014, were shipped from a supplier with nonconforming seal gaps.

An analysis by the manufacturer has shown that a gap between the 12 o'clock core cowl seal and pylon seal that is greater than the 1 mm design requirement could result in fire outside the fire zone. This unsafe condition, if not addressed, could result in an uncontrolled fire, damage to the engine, and damage to the airplane.

Related Service Information

We reviewed GE CF34–8E Service Bulletin (SB) 78–0066 R00, dated December 11, 2017. The SB describes procedures for measuring the width of the RTV filled gap between the thrust reverser fire seals at the 12 o'clock core cowl seal and pylon seal installed on thrust reverser P/Ns 15G0002–013, 15G0002–014, 15G0003–013, and 15G0003–014, and replacing with parts eligible for installation, if needed.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require a one-time inspection of the gap between the core cowl seal and the pylon seal of the thrust reverser for correct gap width, and replacement of the thrust reverser fire seals, if needed.

Costs of Compliance

We estimate that this proposed AD affects 936 engines installed on airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	0.25 work-hours × $85 per hour = $21.25	$0	$21.25	$19,890

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Remove and replace thrust reverser fire seals	2.75 work-hours × $85 per hour = $233.75	$3,228	$3,461.75

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on

products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

General Electric Company: Docket No. FAA–2018–0142; Product Identifier 2018–NE–04–AD.

(a) Comments Due Date

We must receive comments by June 1, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all General Electric Company (GE) CF34–8E turbofan engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7830, Thrust Reverser.

(e) Unsafe Condition

This AD was prompted by a report from GE regarding a quality escape of nonconforming thrust reverser fire seal gaps. We are issuing this AD to inspect for nonconforming thrust reverser fire seal gaps that could result in a fire outside the fire zone. The unsafe condition, if not addressed, could result in an uncontrolled fire, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

(1) For all CF34–8E turbofan engines, before the engine accumulates 8,000 flight hours after the effective date of this AD, perform the following one-time inspection, and, if needed, replace the core cowl seal and pylon seal.

(i) Measure the width of the RTV filled gap between thrust reverser fire seals at the junction between 12 o'clock core cowl seal and pylon seal, at the following half thrust reverser locations: engine 1 left hand (LH) half thrust reverser, part number (P/N) 15G0002–013; engine 2 LH half thrust reverser, P/N 15G0002–014; engine 1 right hand (RH) half thrust reverser, P/N 15G0003–013; and engine 2 RH half thrust reverser P/N 15G0003–014.

(ii) If the gap width between the 12 o'clock core cowl seal and the pylon seal is greater than 1 mm, replace both seals with parts eligible for installation to form a new gap of 1 mm or less, prior to return to service.

(2) You may refer to GE CF34–8E Service Bulletin 78–0066 R00, dated December 11, 2017 for guidance on inspecting and replacing the thrust reverser fire seals.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (i)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local Flight Standards District Office/Certificate Holding District Office.

(i) Related Information

(1) For more information about this AD, contact David Bethka, Aerospace Engineer, ECO Branch, FAA,1200 District Avenue, Burlington, MA 01803; phone: 781–238–7129; fax: 781–238–7199; email: *david.bethka@faa.gov.*

(2) For service information identified in this AD, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; telephone 513–552–3272; email *aviation.fleetsupport@ge.com.* You may view this referenced service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759.

Issued in Burlington, Massachusetts, on April 9, 2018.

Robert J. Ganley,

Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2018–07819 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0276; Product Identifier 2017–NM–079–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 747–100, –100B, –100B SUD, –200B, –200C, –200F, –300, –400, –400D, 747SP, and 747SR, and 747–8 series airplanes. This proposed AD was prompted by reports indicating that additional areas of Boeing Material Specification (BMS) 8–39 flexible urethane foam were found during an inspection required by a related AD. This proposed AD would require inspecting for BMS 8–39 flexible urethane foam insulation in the floor panel assemblies and the power drive unit (PDU) cover assemblies; doing applicable on-condition actions; modifying certain dripshields; and replacing BMS 8–39 foam strips on certain dripshields with BMS 8–371 foam strips. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by June 1, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0276.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0276; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Scott Craig, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3566; email: *Michael.S.Craig@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0276; Product Identifier 2017–NM–079–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We have received reports indicating that additional areas of BMS 8–39 flexible urethane foam were found during the accomplishment of AD 2013–11–04, Amendment 39–17464 (78 FR 33193, June 4, 2013) (''AD 2013–11–04''). AD 2013–11–04 was prompted by in-service reports of burned BMS 8–39 flexible urethane foam, and a report from the airplane manufacturer indicating that airplanes were assembled, throughout various areas of the airplane (including flight deck and cargo compartments), with seals made of BMS 8–39 flexible urethane foam, a material with fire-retardant properties that deteriorate with age. AD 2013–11–04 requires replacing certain seals made of BMS 8–39 flexible urethane foam.

BMS 8–39 flexible urethane foam fire retardants are mixed into, but are not chemically connected with, the remaining components of the foam. Over time, this condition will cause the fire-retardant properties to have decreased effectiveness. The concern is hidden areas where fire cannot easily be detected and suppressed. Aged BMS 8–39 flexible urethane foam exposed to an ignition source provides an unacceptable fuel source for fire propagation. The degradation of the foam increases the potential for an uncontrolled fire below the passenger compartment floor and other locations outside the areas covered by smoke detection and fire protection systems. This condition, if not corrected, could cause an uncontrolled fire leading to loss of control of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed the following Boeing service information.

- Boeing Special Attention Service Bulletin 747–53–2877, dated August 5, 2014, which describes procedures for performing a general visual inspection for BMS 8–39 flexible urethane foam insulation in the floor panel assemblies and the PDU cover assemblies, and applicable on-condition actions.
- Boeing Special Attention Service Bulletin 747–25–3646, Revision 1, dated August 2, 2017, which describes procedures for replacing BMS 8–39 foam strips with BMS 8–371 foam strips on certain dripshields.
- Boeing Special Attention Service Bulletin 747–25–3692, dated June 22, 2016, which describes procedures for modifying and replacing BMS 8–39 foam strips with BMS 8–371 foam strips on certain dripshields.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishment of the actions identified as ''RC'' (required for compliance) in the Accomplishment Instructions of the service information described previously, except as discussed under ''Differences Between this Proposed AD and the Service Information,'' and except for any differences identified as exceptions in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0276.

Differences Between This Proposed AD and the Service Information

Although Boeing Special Attention Service Bulletin 747–25–3646, Revision 1, dated August 2, 2017, and Boeing Special Attention Service Bulletin 747–25–3692, dated June 22, 2016, specify a compliance time of 60 months, this AD specifies a compliance time of 72 months for the actions specified in this service information. The 72-month compliance time is in-line with other ADs addressing the same unsafe condition due to the use of BMS 8–39 flexible urethane foam. We have reviewed the safety impact of the 72-month compliance time and found it acceptable. This compliance time has been coordinated with Boeing.

Costs of Compliance

We estimate that this proposed AD affects 87 airplanes of U.S. registry. We

estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection and replacement	25 work-hours × $85 per hour = $2,125.	Up to $184,460	Up to $186,585	Up to $6,157,305 (33 airplanes affected).
Modification and installation of the dripshields.	10 work-hours × $85 per hour = $850.	Unavailable [1]	$850	$44,200 (52 airplanes affected).
Replacement of the foam on the dripshields.	8 work-hours × $85 per hour = $680.	Unavailable [1]	$680	$4,760 (7 airplanes affected).

[1] We have received no definitive data that would enable us to provide parts cost estimates as the parts and materials are to be supplied by the operator for the actions specified in this AD.

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

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

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2018–0276; Product Identifier 2017–NM–079–AD.

(a) Comments Due Date

We must receive comments by June 1, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company airplanes, certificated in any category, as identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD.

(1) Model 747–100, –100B, –100B SUD, –200B, –200C, –200F, –300, –400, –400D, 747SP, and 747SR series airplanes, as identified in Boeing Special Attention Service Bulletin 747–53–2877, dated August 5, 2014.

(2) Model 747–400, –400D, and 747–8 series airplanes, as identified in Boeing Special Attention Service Bulletin 747–25–3646, Revision 1, dated August 2, 2017.

(3) Model 747–100, –100B, –100B SUD, –200B, –300, 747SP, and 747SR series airplanes, as identified in Boeing Special Attention Service Bulletin 747–25–3692, dated June 22, 2016.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings; 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports indicating that additional areas of Boeing Material Specification (BMS) 8–39 flexible urethane foam were found during an inspection required by a related AD. The degradation of the foam increases the potential for an uncontrolled fire below the passenger compartment floor and other locations outside the areas covered by smoke detection and fire protection systems. We are issuing this AD to detect and replace BMS 8–39 flexible urethane foam in certain areas, which, if exposed to an ignition source, could cause an uncontrolled fire leading to loss of control of the airplane.

(f) Compliance

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

(g) Required Actions

Within 72 months after the effective date of this AD, do all actions identified as ''RC'' (required for compliance) in, and in

accordance with, the Accomplishment Instructions of the applicable service information identified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD.

(1) For airplanes identified in paragraph (c)(1) of this AD: Boeing Special Attention Service Bulletin 747–53–2877, dated August 5, 2014.

(2) For airplanes identified in paragraph (c)(2) of this AD: Boeing Special Attention Service Bulletin 747–25–3646, Revision 1, dated August 2, 2017.

(3) For airplanes identified in paragraph (c)(3) of this AD: Boeing Special Attention Service Bulletin 747–25–3692, dated June 22, 2016.

(h) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g)(2) of this AD, if those actions were performed before the effective date of this AD using Boeing Special Attention Service Bulletin 747–25–3646, dated June 19, 2015.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (i)(4)(i) and (i)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(j) Related Information

(1) For more information about this AD, contact Scott Craig, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3566; email: *Michael.S.Craig@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on March 29, 2018.

Chris Spangenberg,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–07750 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0297; Product Identifier 2017–NM–181–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Airbus Model A319 series airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. This proposed AD was prompted by investigations that revealed that the cover seal of the brake dual distribution valve (BDDV) was damaged and did not ensure efficient sealing. This proposed AD would require identifying the BDDV part number installed on the airplane, and modifying or replacing BDDVs having certain part numbers. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by June 1, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0297; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0297; Product Identifier 2017–NM–181–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2017–0119, dated July 11, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus Model A319 series airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The MCAI states:

In 1998, an operator experienced a dual loss of braking systems. Investigation results revealed that the cover seal of the BDDV was damaged and did not ensure the sealing efficiency.

This condition, if not corrected, could lead to water ingestion in the BDDV, freezing of the BDDV in flight, and consequent loss of braking system function after landing, possibly resulting in damage to the aeroplane and injury to occupants.

To address this potential unsafe condition, Airbus issued Alert Operator Telex (AOT) 32–19 and Service Bulletin (SB) A320–32–1199, providing instructions for repetitive functional tests. In addition, Airbus developed mod 28301 and published SB A320–32–1203 to provide modification instructions.

Consequently, DGAC France issued AD 2000–258–146 [which corresponds to FAA AD 2001–15–10, Amendment 39–12344 (66 FR 39413, dated July 31, 2001) (''AD 2001–15–10'')] to require repetitive functional tests as a temporary solution (valid for a period of 15 months) and modification of the BDDV with a new cover and installation of a draining tube with a cap, which was terminating action for the repetitive functional tests. For pre-mod 27833 and pre-SB A320–32–1200 aeroplanes, repetitive inspections per SB A320–32–1199 were required as interim action, prior to the terminating action modification per SB A320–32–1203.

After that [DGAC] AD was issued, following a new event, Airbus developed a new modification of the BDDV drain tube which leaves it open, ensuring continuous drainage of any ingested water, thereby preventing freezing of the brake system.

Consequently, EASA issued AD 2014–0251 (later revised), partially retaining the requirements of DGAC France AD 2000–258–146, which was superseded, and requiring an additional modification of the BDDV drain tube and re-identification of the BDDV.

Since EASA AD 2014–0251R1 [which corresponds to FAA AD 2016–06–13, Amendment 39–18444 (81 FR 17365, dated March 29, 2016) (''AD 2016–06–13'')] was issued, comments were received that indicated a need for correction and clarification. Consequently, this [EASA] AD retains the requirements of EASA AD 2014–0251R1, which is superseded, and expands the list of BDDV Part Numbers (P/N) which must be removed from service and are no longer eligible for installation on an aeroplane [and includes replacing affected part numbers as an option]. This [EASA] AD also clarifies the intended requirements of EASA AD 2014–0251 and introduces editorial changes, not affecting the requirements.

Paragraph (1) of the MCAI is addressed in paragraphs (e) and (f) of FAA AD 2001–15–10; Paragraph (2) of the MCAI is addressed in paragraph (g) of FAA AD 2016–06–13.

This NPRM would not supersede AD 2001–15–10 and AD 2016–06–13. Rather, we have determined that a stand-alone AD would be more appropriate to address the changes in the MCAI. This NPRM would require identifying the BDDV part number installed on the airplane, and modifying or replacing BDDVs having certain part numbers.

Doing the proposed actions would terminate the requirements in paragraphs (e) and (f) of AD 2001–15–10, and would terminate all of the requirements of AD 2016–06–13.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0297.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A320–32–1203, Revision 02, dated February 9, 2001. This service information describes procedures for identifying the BDDV part number installed on the airplane, and modifying or replacing BDDVs having certain part numbers.

Airbus has also issued Service Bulletin A320–32–1415, Revision 02, dated December 10, 2015. This service information describes procedures for modifying and re-identifying the BDDV. The modification includes modifying the drain hose of the BDDV, and doing all related investigative and corrective actions if applicable. The related investigative actions include an inspection for corrosion. Corrective actions include replacing the BDDV.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Costs of Compliance

We estimate that this proposed AD affects 1,136 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Identification and modification or replacement	6 work-hours × $85 per hour = $510	$395	$905	$1,028,080

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

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that

section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus: Docket No. FAA–2018–0297; Product Identifier 2017–NM–181–AD.

(a) Comments Due Date

We must receive comments by June 1, 2018.

(b) Affected ADs

This AD affects AD 2001–15–10, Amendment 39–12344 (66 FR 39413, dated July 31, 2001) (''AD 2001–15–10''), and AD 2016–06–13, Amendment 39–18444 (81 FR 17365, dated March 29, 2016) (''AD 2016–06–13'').

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1) through (c)(3) of this AD, certificated in any category, all manufacturer serial numbers, except those on which Airbus Modification 26925 has been embodied in production, which introduces a modified alternate braking system that removes the brake dual distribution valve (BDDV).

(1) Airbus Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(2) Airbus Model A320–211, –212, –214, –231, –232, and –233 airplanes.

(3) Airbus Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Reason

This AD was prompted by investigations that revealed that the cover seal of the brake dual distribution valve (BDDV) was damaged and did not ensure efficient sealing. We are issuing this AD to prevent water ingestion in the BDDV, freezing of the BDDV in flight, and consequent loss of braking system function after landing. These conditions could possibly result in damage to the airplane and injury to occupants.

(f) Compliance

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

(g) Identification and Modification or Replacement

Within 3 months after the effective date of this AD, identify the BDDV part number installed on the airplane. For each affected BDDV part number specified in figure 1 to paragraphs (g) and (h) of this AD, within 3 months after the effective date of this AD, do the actions in paragraph (g)(1), (g)(2), or (g)(3) of this AD. A review of airplane maintenance records is acceptable to identify the BDDV part number if the part number of the BDDV can be conclusively determined from that review.

Figure 1 to paragraphs (g) and (h) of this AD – *Affected BDDV part number*

P/N				
A25434005-1	A25434005-100	A25434005-101	A25434006-1	A25434006-100
A25434005-2	A25434005-200	A25434005-201	A25434006-2	A25434006-101
A25434005-3	A25434005-300	A25434005-301	A25434006-3	A25434006-200
A25434005-4	A25434005-400	A25434005-401		

(1) Modify and re-identify the affected BDDV, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–32–1203, Revision 02, dated February 9, 2001.

(2) Modify and re-identify the affected BDDV, and do all applicable related investigative and corrective, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–32–1415, Revision 02, dated December 10, 2015. Do all applicable related investigative and corrective actions before further flight.

(3) Replace the affected BDDV with a BDDV having a part number not specified in figure 1 to paragraphs (g) and (h) of this AD, or a part number specified as 'new P/N' in figure 2 to paragraphs (g)(3) and (h)(2) of this AD. Do the replacement using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

Figure 2 to paragraphs (g)(3) and (h)(2) of this AD – *BDDV part number re-identification*

Old P/N	New P/N
A25434006-3	A25434006-3000
A25434005-101	A25434005-1010
A25434005-201	A25434005-2010
A25434005-301	A25434005-3010
A25434005-401	A25434005-4010
A25434006-101	A25434006-1010

(h) Parts Installation Prohibition

As of the applicable time specified in paragraph (h)(1) or (h)(2) of this AD, no person may install a BDDV having a part number specified in figure 1 to paragraphs (g) and (h) of this AD, on any airplane.

(1) For any airplane that, on the effective date of this AD, has a BDDV installed with a part number specified in figure 1 to paragraphs (g) and (h) of this AD: After modification of the airplane, as required by paragraph (g) of this AD.

(2) For any airplane that, on the effective date of this AD, has a BDDV installed with a part number specified as 'new P/N' in figure 2 to paragraphs (g)(3) and (h)(2) of this AD, or has a BDDV installed with a part number not specified in figure 1 to paragraphs (g) and (h) of this AD: As of the effective date of this AD.

(i) Terminating Action for Other ADs

(1) Doing the actions in paragraph (g) of this AD terminates the requirements in paragraphs (e) and (f) of AD 2001–15–10.

(2) Doing the actions in paragraph (g) of this AD terminates all of the requirements of AD 2016–06–13.

(j) Credit for Previous Actions

(1) This paragraph provides credit for actions required by paragraph (g)(1) of this AD, if those actions were performed before the effective date of this AD using the service information in paragraphs (j)(1)(i) and (j)(1)(ii) of this AD.

(i) Airbus Service Bulletin A320–32–1203, dated June 4, 1999, which was incorporated by reference in AD 2001–15–10.

(ii) Airbus Service Bulletin A320–32–1203, Revision 01, dated October 12, 2000.

(2) This paragraph provides credit for actions required by paragraph (g)(2) of this AD, if those actions were performed before the effective date of this AD using the service information in paragraphs (j)(2)(i) and (j)(2)(ii) of this AD.

(i) Airbus Service Bulletin A320–32–1415, dated September 2, 2014, which was incorporated by reference in AD 2016–06–13.

(ii) Airbus Service Bulletin A320–32–1415, Revision 01, dated April 23, 2015.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (l)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2017–0119, dated July 11, 2017, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0297.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

(3) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on March 30, 2018.

Chris Spangenberg,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–07637 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0101; Airspace Docket No. 18–AGL–4]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Lansing, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace extending upward from 700 feet above the surface at Capital Region International Airport, Lansing, MI. The FAA is proposing this action as a result of an airspace review do to the decommissioning of the Lansing VHF omnidirectional range (VOR) navigation aid as part of the VOR Minimum Operational Network (MON) Program. The geographic coordinates and name of the airport would also be updated to coincide with the FAA's

aeronautical database. An editorial change would also be made to the legal designation by removing the city from the airport name.

DATES: Comments must be received on or before June 1, 2018.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2018–0101; Airspace Docket No. 18–AGL–4, at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

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

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2018–0101; Airspace Docket No. 18–AGL–4.'' The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRMs

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 by amending the Class E airspace extending upward from 700 feet above the surface to within a 6.8-mile radius (increased from a 6.7-mile radius) at Capital Region International Airport (formerly Capital City Airport), Lansing, MI; removing the extension to the east of the airport associated with the ARTDA LOM; adding an extension within 2 miles each side of the 091° bearing from the airport from the 6.8-mile radius to 10.4 mile east of the airport; and adding an extension within 4 miles each side of the 233° from the airport from the 6.8-mile radius to 10.5 miles southwest of the airport.

The name of the airport would also be updated from Capital City Airport to Capital Region International Airport, and the geographic coordinates of the airport would be updated to coincide with the FAA's aeronautical database. Additionally, an editorial change would be made removing the name of the city associated with the airport in the legal designation to comply with a recent change to FAA Order 7400.2L, Procedures for Handling Airspace Matters.

This action is necessary as the result of airspace review do to the decommissioning of the Lansing VOR as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are

necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

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

* * * * *

AGL MI E5 Lansing, MI [Amended]

Capital Region International Airport, MI
(Lat. 42°46′43″ N, long. 84°35′10″ W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Capital Region International Airport, and within 2.0 miles each side of the 091° bearing from the airport extending from the 6.8-mile radius to 10.4 mile east of the airport, and within 4.0 miles each side of the 233° bearing from the airport extending from the 6.8-mile radius to 10.5 miles southwest of the airport.

Issued in Fort Worth, Texas, on April 9, 2018.

Christopher L. Southerland,

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

[FR Doc. 2018–07903 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0280; Airspace Docket No. 17–AGL–27]

RIN 2120–AA66

Proposed Amendment of VOR Federal Airways V–170 and V–219 in the Vicinity of Fairmont, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend VHF Omnidirectional Range (VOR) Federal airways V–170 and V–219 in the vicinity of Fairmont, MN. The modifications are necessary due to the planned decommissioning of the Fairmont, MN (FRM), VOR navigation aid (NAVAID), which provides navigation guidance for portions of the affected air traffic service (ATS) routes. The Fairmont VOR is being decommissioned as part of the VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before June 1, 2018.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1(800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2018–0280; Airspace Docket No. 17–AGL–27 at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.*

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

Comments Invited

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

Communications should identify both docket numbers (FAA Docket No. FAA–2018–0280; Airspace Docket No. 17–AGL–27) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *http://www.regulations.gov.*

Commenters 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–2018–0280; Airspace Docket No. 17–AGL–27.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of 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.

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 **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 during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Blvd., Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

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

Background

The FAA is planning decommissioning activities for the Fairmont, MN (FRM), VOR in 2019 as one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the final policy statement notice, ''Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the **Federal Register** of July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082. Although the VOR portion of the Fairmont, MN, VOR/Distance Measuring Equipment (DME) NAVAID is planned for decommissioning, the DME portion is being retained. The ATS routes effected by the Fairmont VOR are VOR Federal airways V–170 and V–219.

With the planned decommissioning of the Fairmont VOR, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected airways. As such, proposed modifications to V–170 and V–219 would result in gaps in the route structures. To overcome the gaps, instrument flight rules (IFR) traffic could use adjacent VOR Federal airways V–24, V–250, and V–398 between the Worthington, MN, VOR/DME and Rochester, MN, VOR/DME or Federal airways V–100, V–175, V–250, and V–456 between the Sioux City, IA, VOR/Tactical Air Navigation (VORTAC) and Mankato, MN, VOR/DME to circumnavigate the affected area. Additionally, IFR traffic could file point to point through the affected area using fixes that will remain in place, or receive air traffic control (ATC) radar vectors through the area. Visual flight rules pilots who elect to navigate via the airways through the affected area could also take advantage of the adjacent VOR Federal airways or ATC services listed previously.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to modify VOR Federal airways V–170 and V–219. The planned decommissioning of the Fairmont, MN, VOR has made these actions necessary. The proposed VOR Federal airway changes are outlined below.

V–170: V–170 currently extends between the Devils Lake, ND, VOR/DME and the Salem, MI VORTAC; and between the Erie, PA, VORTAC and the intersection of the Andrews 060° and Baltimore, MD, 165° radials (POLLA fix); excluding the airspace within R–5802 when active. In a separate rulemaking action, the FAA is removing the airway segment between the Erie, PA, VORTAC and the Bradford, PA, VOR/DME effective May 24, 2018 (83 FR 13404, March 29, 2018). The FAA now proposes to remove the airway segment between the Worthington, MN, VOR/DME and the Rochester, MN, VOR/DME. The unaffected portions of the existing airway would remain as charted.

V–219: V–219 currently extends between the Hayes Center, NE, VORTAC and the Mankato, MN, VOR/DME. The FAA proposes to remove the airway segment between the Sioux City, IA, VORTAC and the Mankato, MN, VOR/DME. The unaffected portions of the existing airway would remain as charted.

All radials in the route descriptions below are unchanged and stated in True degrees.

VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.11B dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airways listed in this document would be subsequently published 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 Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that 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 will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–170 [Amended]

From Devils Lake, ND; INT Devils Lake 187° and Jamestown, ND, 337° radials; Jamestown; Aberdeen, SD; Sioux Falls, SD; to Worthington, MN. From Rochester, MN; Nodine, MN; Dells, WI; INT Dells 097° and Badger, WI, 304° radials; Badger; INT Badger 121° and Pullman, MI, 282° radials; Pullman; to Salem, MI. From Bradford, PA; Slate Run, PA; Selinsgrove, PA; Ravine, PA; INT Ravine 125° and Modena, PA, 318° radials; Modena; Dupont, DE; INT Dupont 223° and Andrews, MD, 060° radials; to INT Andrews 060° and Baltimore, MD, 165° radials. The airspace within R–5802 is excluded when active.

* * * * *

V–219 [Amended]

From Hayes Center, NE; INT Hayes Center 059° and Wolbach, NE, 251° radials; Wolbach; Norfolk, NE; to Sioux City, IA.

Issued in Washington, DC, on April 9, 2018.

Rodger A. Dean Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2018–07902 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 30

[189A2100DD/AAKC001030/ A0A501010.999900 253G]

Bureau of Indian Education Standards, Assessments, and Accountability System Negotiated Rulemaking Committee Establishment; Proposed Membership

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed membership of Committee and request for nominations.

SUMMARY: The U.S. Department of the Interior is announcing the proposed members to form the Bureau of Indian Education (BIE) Standards, Assessments, and Accountability System Negotiated Rulemaking Committee (Committee) which will advise the Secretary of the Interior (Secretary) through the BIE on a proposed rule to revise the Adequate Yearly Progress regulation as previously announced in the **Federal Register**. This notice solicits comments on the proposed membership, and invites additional nominations for Committee members who will adequately represent the interests that are likely to be significantly affected by the proposed rule. The Secretary also proposes to appoint Federal representatives to the Committee as listed.

DATES: Comments must be submitted no later than May 17, 2018.

ADDRESSES: Send comments and nominations to the Designated Federal Officer, Ms. Sue Bement, Education Program Specialist, Bureau of Indian Education, by any of the following methods:

- (Preferred method) Email to: *BIEcomments@bia.gov*;
- Mail, hand-carry or use an overnight courier service to the Designated Federal Officer, Ms. Sue Bement, c/o The Office of Regulatory Affairs and Collaborative Action, 1001 Indian School Road NW, Suite 312, Albuquerque, NM 87104.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer, Ms. Sue Bement, Bureau of Indian Education; email: *BIEcomments@bia.gov*; phone: (952) 851–5427.

SUPPLEMENTARY INFORMATION:

Background

The purpose of the BIE Committee is to serve as an advisory committee under the Federal Advisory Committee Act (FACA) and the Negotiated Rulemaking Act (NRA). Pursuant to the **Federal Register** notice of intent (82 FR 43199), the Secretary has selected 13 Tribal representatives and 5 Federal representatives for the Committee, for a proposed total of 18 members.

Every Student Succeeds Act

The Every Student Succeeds Act (ESSA) reauthorizes and amends the Elementary and Secondary Education Act of 1965 (ESEA). ESEA Section 8204, as amended by ESSA directs the Secretary of the Interior, in consultation with the Secretary of Education, if so requested, to use a negotiated rulemaking process to develop regulations for implementation of the Secretary of the Interior's responsibility to define standards, assessments, and an accountability system for Bureau-funded schools. The Committee will recommend regulations that will replace the existing regulations at 25 CFR part 30 and implement the Secretary's new statutory responsibility to define standards, assessments, and an accountability system for Bureau-funded schools consistent with ESEA section 1111, as amended, on a national, regional, or Tribal basis, as appropriate, taking into account the unique circumstances and needs of such schools and the students served by such schools.

ESEA section 8204 also provides that if a Tribal governing body or school board of a Bureau-funded school determines the requirements established by the Secretary of the Interior are inappropriate, they may waive, in part or in whole, such requirements. Where such requirements are waived, the Tribal governing body or school board must, within 60 days, submit to the Secretary of the Interior a proposal for alternative standards, assessments, and an accountability system, if applicable, consistent with ESEA section 1111. The proposal will be approved by the Secretary of the Interior and the Secretary of Education, unless the proposed standards, assessments, and accountability system do not meet the requirements of ESEA section 1111, taking into account the unique circumstances and needs of such school or schools and the students served. Additionally, a Tribal governing body or school board of a Bureau-funded school seeking a waiver may request, technical assistance from the Secretary of the Interior and the Secretary of Education.

Proposed Work of the Committee

The objectives of the Committee are to represent the interests that will be significantly affected by the final regulations, negotiate in good faith, and reach consensus, where possible, on recommendations to the Secretary for the proposed regulations.

The Committee will be charged, consistent with ESEA section 8204, with developing draft regulations to implement the Secretary's responsibility to define the standards, assessments, and an accountability system, consistent with ESEA Section 1111, for Bureau-funded schools. The draft regulations will be considered by the Secretary and subject to government-to-government consultation. As a part of its deliberations, the Committee will consider the appropriate scope of the draft regulations, *e.g.,* national, regional, or Tribal basis, as appropriate, taking

into account the unique circumstances and needs of such schools and the students served by such schools, and how BIE will implement such regulations.

The BIE encourages Tribal self-determination in Native education, by encouraging governing Tribes or school boards to develop alternative standards, assessments, and an accountability system, and by providing technical assistance. Therefore, the Committee will also be asked to provide recommendations on how the BIE could best provide technical assistance under ESEA section 8204 to Tribes who opt to exercise their authority to waive in part or in whole the Secretary's definition of standards, assessments, and accountability system.

Since the contemplated regulations must be in place as soon as possible, the Committee will be expected to meet frequently within a short time frame. The BIE currently anticipates up to four meetings, with each meeting lasting two to three days in length. The BIE has dedicated resources required to: Ensure the Committee is able to conduct meetings, provide technical assistance, and provide any additional support required to fulfill the Committee's responsibilities.

Proposed Tribal Committee Members

On September 14, 2017, the BIE published a **Federal Register** notice of intent (82 FR 43199) requesting comments and nominations for Tribal representatives for the Committee. The comment period for that notice of intent closed October 16, 2017.

Within the notice, the BIE solicited comments on the proposal to establish the Committee, including comments on any additional interests not identified. The BIE solicited nominations from Tribes whose students attend Bureau-funded schools operated by either BIE or by the Tribe through a contract or grant who would be affected by the final rule to nominate a representative and alternate to serve when the representative is unavailable for membership on the Committee. The BIE also invited nominations for Committee members who will adequately represent the interests that are likely to be significantly affected by the proposed rule such as: Students enrolled, or parents of students enrolled at the 174 Bureau-funded schools, school teachers, and administrators, Tribes, and Indian communities served by these schools.

The proposed Committee was selected based upon nominations submitted through the process identified in the **Federal Register** (82 FR 43199) dated September 14, 2017, under the ''Nominations'' section. The Secretary did not consider nominations that were received in any other manner or were received after the close of the comment period.

The Secretary proposes the following Tribal representatives for the Committee:

Proposed committee member	Nominated by
Gloria Coats-Kitsopoulos, Superintendent, American Horse School	Oglala Sioux Tribe (South Dakota).
Charles Cuny, Superintendent, Little Wound School	Oglala Sioux Tribe (South Dakota).
Michael Debrieo, Principal, Kha'p'o Community School	Santa Clara Indian Pueblo (New Mexico).
Ronald Etheridge, Deputy Executive Director of Education Services, Cherokee Nation.	Intertribal Council of the Five Civilized Tribes (Oklahoma).
Leslie Harper-Liberty, Government Relations Specialist, Leech Lake Band of Ojibwe.	Leech Lake Band of Ojibwe (Minnesota).
Tommy Lewis, Jr., Superintendent of Schools, Navajo Nation	National Indian Education Association (Arizona).
Jennifer Lynn McLeod Tyson, Tribal Councilwoman, Sault Ste. Marie Tribe of Chippewa Indians.	Sault Ste. Marie Tribe of Chippewa Indians (Michigan).
Patricia Sandoval, Director of Planning and Evaluation, Santa Fe Indian School	Pueblo of Laguna (New Mexico).
Delima ''Bonnie'' Rose Payer, Teacher, Ojibwa Indian School on the Turtle Mountain Reservation.	American Federation of Teachers (North Dakota).
Richard St. Germaine, Commissioner, Education for the Mille Lacs Band of Ojibwe.	Mille Lacs Band of Ojibwe (Minnesota).
Sherry Tubby, Exceptional Education Coordinator, Choctaw Tribal Schools	Mississippi Band of Choctaw Indians (Mississippi).

The Secretary proposes the following alternate Tribal representatives for the Committee:

Proposed alternate committee member	Nominated by
Lucinda Campbell, Lukachukai Community Board of Education, Inc.	Diné Grant Schools Association (Arizona).
Franklin No Runner, Superintendent, St. Stephens Indian School	Northern Arapaho Business Council (Wyoming).

Proposed Federal Committee Members

The Designated Federal Officer for the Committee will be Ms. Sue Bement, Bureau of Indian Education. The Secretary proposes the following Federal representatives for the Committee:

Name	Affiliation
Jeffrey Hamley, Associate Deputy Director, Division of Performance and Accountability.	Bureau of Indian Education.
Lora Braucher, Superintendent, Chemawa Indian School	Bureau of Indian Education.
Brian Quint, Attorney-Advisor	Office of the Solicitor.

The Secretary proposes the following alternate Federal representatives for the Committee:

Name	Affiliation
Jimmy Hastings, Education Program Administrator	Bureau of Indian Education.
Brenda Riel, Attorney-Advisor	Office of the Solicitor.

Comments

The Secretary solicited comments on the proposal to establish the Committee and received one response from the National Indian Education Association (NIEA) that was submitted through the process identified in the **Federal Register** (82 FR 43199) dated September 14, 2017. The Secretary did not consider comments that were received in any other manner or were received after the close of the comment period.

The comments received from NIEA: (1) Support the proposal to form a negotiated rulemaking committee, (2) encourage the Secretary to include Native educators, researchers, and evaluators on the Committee, and (3) encourage the Secretary to ensure that representatives are served by Bureau-funded schools.

Both the Secretary and the BIE believe the proposed representatives address NIEA's comments to ensure the Native students are best supported and evaluated holistically. The proposed representatives carry a wide range of experiences, knowledge, and understanding to support Native students both academically and culturally.

Nominations

If you are a Tribe with Bureau-funded schools, an Indian education organization, or an interested individual, we invite you to comment on the proposed nominations in this notice or to nominate other persons for membership on the Committee. The Committee membership should reflect the diversity of Tribal interests, and Tribes should nominate representatives and alternates who will:

- Have knowledge of school standards, assessments, and accountability systems;
- Have relevant experiences as past or present superintendents, principals, teachers, or school board members;
- Are able to coordinate, to the extent possible, with other interests who may not be represented on the Committee;
- Are able to represent one or more of the specified interests with the authority to embody the views of that or those interest(s), communicate with interested constituents, and have a clear means to reach agreement on behalf of the interest(s);
- Are able to negotiate effectively on behalf of the interest(s) represented;
- Are able to commit the time and effort required to attend and prepare for meetings; and
- Are able to collaborate among diverse parties in a consensus-seeking process.

The Secretary will consider nominations for representatives only if they are nominated through the process identified in this Notice and in the **Federal Register** Notice of Intent (82 FR 43199). The Secretary will not consider any nominations received in any other manner. The Secretary will not consider nominations for Federal representatives; only the Secretary may nominate Federal employees to the Committee.

Nominations must include the following information about each nominee:

(1) A current letter from the entity representing one of the interest(s) identified supporting the nomination of the individual to serve as a representative for the Committee;

(2) A resume reflecting the nominee's qualifications and experience in Indian education; resume to include the nominee's name, Tribal affiliation (if applicable), job title, major job duties, employer, business address, business telephone and fax numbers (and business email address, if applicable);

(3) The interest(s) to be represented by the nominee identified in Section V, in the **Federal Register** (82 FR 43199) published September 14, 2017, and whether the nominee will represent other interest(s) related to this rulemaking;

(4) A brief description of how the nominee will represent the views of the identified interest(s), communicate with constituents, and have a clear means to reach agreement on behalf of the interest(s) they are representing; and

(5) A statement on whether the nominee is only representing one interest or whether the expectation is that the nominee represents a specific group of interests.

To be considered, nominations must be received by the close of business on the date listed in the **DATES** section, at the location indicated in the **ADDRESSES** section.

III. Public Disclosure of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire nomination submission—including your personal identifying information—may be made publically available at any time. While you can ask us in your submission to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: The Elementary and Secondary Education Act of 1965, as amended, 20 U.S.C. 6301 *et seq.*

Dated: April 9, 2018.

John Tahsuda,

Principal Deputy Assistant Secretary—Indian Affairs, Exercising the Authority of the Assistant Secretary—Indian Affairs.

[FR Doc. 2018–07922 Filed 4–16–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2018–0320]

RIN 1625–AA08

Special Local Regulation; Monongahela River (MM 0.22), Allegheny River (MM 0.8), and Ohio River (0.8), Pittsburgh, PA.

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a special local regulation for certain navigable waters of the Allegheny, Monongahela, and Ohio Rivers in the vicinity of Pittsburgh, PA. This action is necessary to provide for the safety of life on these navigable waters during the weekend of the Luke Bryan concert at Heinz Field. This proposed rulemaking would prohibit persons and vessels from loitering, anchoring, stopping, mooring, remaining, or drifting in any manner

that impedes safe passage of another vessel to any launching ramp, marina, or fleeting area unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative. In addition, this proposed rulemaking would prohibit persons and vessels from loitering, anchoring, stopping, or drifting more than 100 feet from any river bank unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 2, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0320 using the Federal eRulemaking Portal at *http://www.regulations.gov*. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Petty Officer Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email *Jennifer.L.Haggins@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

Heinz Field notified the Coast Guard that it would be holding a concert from 4 p.m. to 11 p.m. on June 30, 2018. Heinz Field is located in close proximity to the banks of the Ohio and Allegheny Rivers, which is a high vessel traffic area used by both commercial and recreational vessels. Due to the proximity of Heinz Field to these waterways, it will be a destination for many recreational vessels to anchor and loiter throughout the concert weekend of June 29, 2018 to July 1, 2018. The Coast Guard is concerned about possible collisions that could occur in this area and the impact of vessel congestion on maritime commerce due to transit delays. The Captain of the Port Marine Safety Unit Pittsburgh (COTP) has determined that this special local regulation is necessary to maintain an open navigation channel and ensure the safety of vessels and these navigable waters during the concert weekend.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters adjacent to Heinz Field on the Allegheny, Monongahela, and Ohio Rivers before, during, and after the Luke Bryan concert weekend. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1233.

The Coast Guard is issuing this notice of proposed rulemaking (NPRM) with a 15-day prior notice and opportunity to comment pursuant to section (b)(3) of the Administrative Procedure Act (APA) (5 U.S.C. 553). This provision authorizes an agency to publish a rule in less than 30 days before its effective date for ''good cause found and published with the rule.'' Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for publishing this NPRM with a 15-day comment period because it is impractical to provide a 30-day comment period. This proposed special local regulation is necessary to ensure the safety of vessels and persons during the concert weekend. It is impracticable to publish an NPRM with a 30-day comment period because we must establish this special local regulation by June 29, 2018. A 15-day comment period would allow the Coast Guard to provide for public notice and comment, but also publish a rule, if adopted, soon enough that the length of the notice and comment period does not compromise public safety.

III. Discussion of Proposed Rule

The COTP proposes to establish a special local regulation for all navigable waters of the Allegheny, Monongahela, and Ohio Rivers between the Ninth Street Highway Bridge at mile marker (MM) 0.8, Allegheny River, Fort Pitt Highway Bridge at MM 0.22, Monongahela River, and West End-North Side Highway Bridge at MM 0.8, Ohio River. The duration of the special local regulation is intended to ensure the safety of vessels on these navigable waters before, during, and after the concert weekend. This proposed rule would apply to any vessel operating within the area, including a naval or public vessel, except a vessel engaged in law enforcement, servicing aids to navigation, or surveying, maintaining, or improving waters within the regulated area. No vessel would be permitted to loiter, anchor, stop, moor, remain or drift in any manner that impedes safe passage of another vessel to any launching ramp, marina, or fleeting area unless authorized by the COTP or a designated representative. In addition, no vessel or person would be permitted to loiter, anchor, stop, remain, or drift more than 100 feet from any riverbank unless authorized by the COTP or a designated representative. They may be contacted on VHF–FM Channel 16. Persons and vessels permitted to enter this regulated area must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size and location of the special local regulation. The special local regulation will impact a small section of the Allegheny, Monongahela, and Ohio Rivers, less than three total miles. Moreover, the special local regulation will not stop vessels from transiting the area, it will only establish certain areas where vessels are prohibited from loitering, anchoring, stopping, remaining, or drifting because it impedes navigation near launching ramps, marinas, and fleeting areas, or commercial traffic in the rivers. Moreover, the Coast Guard would issue Broadcast Notice to Mariners (BNMs) via VHF–FM marine channel 16 about the regulated area and the rule would allow vessels to seek permission to enter the regulated area.

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 regulated area 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 Management Directive 023–01 and Commandant Instruction M16475.lD, 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 special local regulation that prohibits vessels from loitering, anchoring, stopping, remaining or drifting more than 100 feet from any bank. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of Implementation of the National Environmental Policy Act, Department of Homeland Security Instruction Manual 023–01–001–01. A preliminary environmental analysis checklist and Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

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

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

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that 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 100

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 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add § 100.T08–0320 to read as follows:

§ 100.T08–0320 Special Local Regulation; Monongahela River (MM 0.22), Allegheny River (MM 0.8), and Ohio River (MM 0.8), Pittsburgh, PA.

(a) *Location.* The following is a special local regulation for all navigable waters of the Allegheny, Monongahela, and Ohio Rivers between the Ninth Street Highway Bridge at mile marker (MM) 0.8, Allegheny River, Fort Pitt Highway Bridge at MM 0.22, Monongahela River, and West End-North Side Highway Bridge at MM 0.8, Ohio River.

(b) *Applicability.* This section applies to any vessel operating within the area, including a naval or public vessel, except a vessel engaged in:

(1) Law enforcement;

(2) Servicing aids to navigation; or

(3) Surveying, maintaining, or improving waters within the regulated area.

(c) *Regulations.* (1) In accordance with the general regulations in § 100.801 of this part, no vessel shall loiter, anchor, stop, moor, remain or drift in any manner as to impede safe passage of another vessel to any launching ramp, marina, or fleeting area unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative. They may be contacted on VHF–FM Channel 16.

(2) No vessel shall loiter, anchor, stop, moor, remain or drift at any time more than 100 feet from any river bank within the regulated area unless authorized by the COTP or a designated representative.

(3) Persons and vessels permitted to enter this regulated area must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(4) Persons and vessels permitted to enter this regulated area must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(d) *Effective period.* This section will be effective from 4 p.m. on June 29, 2018 through noon on July 1, 2018.

(e) *Informational broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs) of the enforcement period for the regulated area as well as any changes in the dates and times of enforcement.

Dated: April 12, 2018.

F.M. Smith,

Lieutenant Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh, Acting.

[FR Doc. 2018–08032 Filed 4–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0038]

RIN 1625–AA00

Safety Zones; Coast Guard Sector Upper Mississippi River Annual and Recurring Safety Zones Update

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend its safety zone regulations for annual events in Coast Guard Sector Upper Mississippi River. This proposed rule would add one new recurring safety zone, remove four safety zones, and amend the sponsor/name, date, and/or safety zones for three recurring safety zones already listed in the current table. This action is necessary to protect spectators, participants, and vessels from the hazards associated with annual marine events. This proposed rulemaking would restrict vessel traffic from the safety zones during the events unless authorized by the Captain of the Port Sector Upper Mississippi River or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 17, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0038 using the Federal eRulemaking Portal at *http://www.regulations.gov*. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Lieutenant Commander Sean Peterson, Chief of Prevention, U.S. Coast Guard; telephone (314) 269–2568, email *Sean.M.Peterson@uscg,mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

The Captain of the Port Sector Upper Mississippi River (COTP) proposes to amend 33 CFR 165.801 to update the table of annual fireworks displays and other marine-related events in Coast Guard Sector Upper Mississippi River. The current list of annual and recurring safety zones in Sector Upper Mississippi River is published in Table 2 of 33 CFR 165.801. That most recent table was created through the final rule published on June 21, 2017 (82 FR 28235). The current table in 33 CFR 165.801 needs to be amended to include new safety zones expected to recur annually or biannually, remove safety zones no longer recurring, and provide new information on existing safety zones.

The proposed annually recurring safety zones are necessary to provide for the safety of life on navigable waters during the events. Based on the nature of these marine events, large numbers of participants and spectators, and event locations, the COTP has determined that the events listed in this proposed rule could pose a risk to participants or waterways users if the normal vessel traffic were to interfere with the events. Possible hazards include risks of injury or death from near or actual contact among participant vessels and spectators or mariners traversing through the safety zone. In order to protect the safety of all waterway users, including event participants and spectators, this proposed rule would establish safety zones for the time and location of each marine event.

This purpose of this proposed rulemaking is to ensure the safety of vessels on the navigable waters in the safety zones during the scheduled events. Vessels would not be permitted to enter the safety zone unless authorized by the COTP or a designated representative. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to amend its safety zone regulations for annual events in Coast Guard Sector Upper Mississippi River listed in Table 2 of 33 CFR 165.801. This section requires amendment from time to time to properly reflect the recurring safety zone regulations in Sector Upper Mississippi River. This rule would add one new recurring safety zone, remove four no longer recurring safety zones, and amend the sponsor/name, date, and/or safety zones for three recurring safety zones already listed in the current table. Other than this one new safety

zone, four removed safety zones, and 3 changes to the sponsor/name, date, and/or safety zones of certain events, the regulations of 33 CFR 165.801 and the other provisions in Table 2 of § 165.801 would remain unchanged.

The Coast Guard proposes to revise regulations at 33 CFR 165.801 Table 2 by adding one new safety zone. The safety zone being added to Table 2 is below:

Date	Sponsor/name	Sector Upper Mississippi River location	Safety zone
2 days—3rd Weekend in July.	Kentucky Drag Boat Association/Evansville, IL Drag Boat Races.	Evansville, IL	Kaskaskia River mile marker 9 to 11.

The Coast Guard also proposes to revise regulations at 33 CFR 165.801 Table 2 by removing the following four existing safety zones that are no longer recurring, with reference by line number to the current Table 2 of 33 CFR 165.801. The four existing safety zones being removed are below:

Line	Date	Sponsor/name	Sector Upper Mississippi River location	Safety zone
3	1 day—2nd Weekend of June.	City of Champlin/Father Hennepin Fireworks Display.	Champlin, MN	Upper Mississippi River mile marker 870.5 to 872.0.
22	1 day—3rd Sunday in June.	Burlington Steamboat Days/Burlington Steamboat Days.	Burlington, IA	Upper Mississippi River mile marker 403.5 to 404.5.
34	1 day—4th of July Weekend.	McGregor/Marquette Chamber Commerce/Independence Day Celebration.	Marquette, IA	Upper Mississippi River mile marker 635.7 to 634.2.
37	2 days—3rd Weekend of September.	Riverside Chamber of Commerce/Riverfest.	Riverside, MO	Missouri River mile marker 371.8 to 372.2.

The Coast Guard also proposes to revise regulations at 33 CFR 165.801 Table 2 by amending three existing safety zones listed in the current table. The amendments involve changes to marine event sponsor/name and/or safety zones, with reference by line number to the current Table 2 of 33 CFR 165.801. The three safety zones being amended are below:

This proposed rule modifies the following three safety zones from the existing Table 2 in § 165.801 as follows:

Line	Date	Sponsor/name	Sector Upper Mississippi River location	Safety zone	Revision
1	1 day—4th Weekend in July.	Marketing Minneapolis LLC/Aquatennial Fireworks.	Minneapolis, MN	Upper Mississippi River mile marker 853.2 to 854.2.	Sponsor/name.
32	1 day—4th of July Weekend.	Grafton Chamber of Commerce/Grafton Chamber 4th of July Fireworks.	Grafton, IL	Upper Mississippi River mile marker 218 to 219.	Safety zone.
41	1 day—4th of July Week.	City of East Moline/City of East Moline Fireworks.	East Moline, IL	Upper Mississippi River mile marker 489.9 to 490.2.	Date and safety zone.

The amendments to this rule are necessary to ensure the safety of vessels and people during annual events taking place on or near navigable waters in Sector Upper Mississippi River. Although this proposed rule would be in effect year-round, the specific safety zones listed in Table 2 of 33 CFR 165.801 would only be enforced during a specified period of time coinciding with the happening of the annual events listed. In accordance with the regulations listed in 33 CFR 165.801(a)–(d), entry into these safety zones is prohibited unless authorized by the COTP or a designated representative. The regulatory text of the updated Table 2 of § 165.801 we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process.

This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the safety zones. These safety zones are limited in size and duration, and are usually positioned away from high vessel traffic zones. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zones, and the rule would allow vessels to seek permission to enter the zones.

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 safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.lD, 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 establishing safety zones limiting access to certain areas under 33 CFR 165 within the COTP Zone. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

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

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

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

§ 165.801 [Amended]

■ 2. In § 165.801, revise Table 2 to read as follows:

TABLE 2 OF § 165.801—SECTOR UPPER MISSISSIPPI RIVER ANNUAL AND RECURRING SAFETY ZONES

Date	Sponsor/name	Sector Upper Mississippi River location	Safety zone
1. 1 day—4th Weekend in July.	Marketing Minneapolis LLC/Aquatennial Fireworks.	Minneapolis, MN	Upper Mississippi River mile marker 853.2 to 854.2.
2. 1 day—4th of July weekend.	Radio Dubuque/Radio Dubuque Fireworks and Air show.	Dubuque, IA	Upper Mississippi River mile marker 581.0 to 583.0.
3. 1 day—4th of July weekend.	Downtown Main Street/Mississippi Alumination.	Red Wing, MN	Upper Mississippi River mile marker 790.8 to 791.2.
4. 1 day—4th of July weekend.	Tan-Tar-A Resort/Tan-Tar-A 4th of July Fireworks.	Lake of the Ozarks, MO	Lake of the Ozarks mile marker 025.8 to 026.2.
5. 1 day—1st weekend of September.	Tan-Tar-A Resort/Tan-Tar-A Labor Day Fireworks.	Lake of the Ozarks, MO	Lake of the Ozarks mile marker 025.8 to 026.2.
6. 1 day—Last Sunday in May.	Tan-Tar-A Resort/Tan-Tar-A Memorial Day fireworks.	Lake of the Ozarks, MO	Lake of the Ozarks mile marker 025.8 to 026.2.
7. 1 day—4th of July weekend.	Lake City Chamber of Commerce/Lake City 4th of July Fireworks.	Lake City, MN	Upper Mississippi River mile marker 772.4 to 772.8.
8. 1 day—4th of July weekend.	Greater Muscatine Chamber of Commerce/Muscatine 4th of July.	Muscatine, IA	Upper Mississippi River mile marker 455.0 to 456.0.
9. 1 day—Last weekend in June/First weekend in July.	Friends of the River Kansas City/KC Riverfest.	Kansas City, KS	Missouri River mile marker 364.8 to 365.2.
10. 1 day—4th of July weekend.	Louisiana Chamber of Commerce/Louisiana July 4th Fireworks.	Louisiana, MO	Upper Mississippi River mile marker 282.0 to 283.0.
11. 1 day—4th of July weekend.	Guttenberg Development and Tourism/Stars and Stripes River Day.	Guttenberg, IA	Upper Mississippi River mile marker 615.0 to 615.5.
12. 4 days—1st or 2nd week of July.	Riverfest, Inc./La Crosse Riverfest	La Crosse, WI	Upper Mississippi River mile marker 697.5 to 698.5 (Wisconsin).
13. 1 day—2nd weekend in July.	Prairie du Chien Area Chamber of Commerce/Prairie du Chien Area Chamber Fireworks.	Prairie du Chien, WI	Upper Mississippi River mile marker 635.2 to 635.7.
14. 1 day—4th of July weekend.	JMP Radio/Red White and Boom Peoria	Peoria, IL	Illinois River mile marker 162.5 to 162.1.
15. 1 day—Last weekend in June/First weekend in July.	Hudson Boosters/Hudson Booster Days	Hudson, WI	St. Croix River mile marker 016.8 to 017.2.
16. 2 days—4th of July weekend.	City of St. Charles/St. Charles Riverfest	St. Charles, MO	Missouri River mile marker 028.2 to 028.8.
17. 1 day—4th of July weekend.	Minneapolis Park and Recreation Board/Red, White, and Boom Minneapolis.	Minneapolis, MN	Upper Mississippi River mile marker 853.5 to 854.5.
18. 1 day—4th of July weekend.	Davenport One Chamber/Red White and Boom.	Davenport, IA	Upper Mississippi River mile marker 482.0 to 482.7.
19. 2 days—3rd weekend of July.	Amelia Earhart Festival Committee/Amelia Earhart Festival.	Kansas City, KS	Missouri River mile marker 422.0 to 424.5.
20. 1 day—4th of July weekend.	Alton Exposition Commission/Mississippi Fireworks Festival.	Alton, IL	Upper Mississippi River mile marker 202.5 to 203.0.
21. 1 day—Last Sunday in May.	Lodge of the Four Seasons/Lodge of the Four Seasons Memorial Day Fireworks.	Lake of the Ozarks, MO	Lake of the Ozarks mile marker 013.8 to 014.2.
22. 1 day—First weekend of September.	Lodge of the Four Seasons/Labor Day Fireworks.	Lake of the Ozarks, MO	Lake of the Ozarks mile marker 013.8 to 014.2.
23. 1 day—4th of July weekend.	Lodge of the Four Seasons/Lodge of the Four Seasons 4th of July.	Lake of the Ozarks, MO	Lake of the Ozarks mile marker 013.8 to 014.2.
24. 2 days—3rd weekend in July.	Hasting Riverboat Days/Rivertown Days	Hasting, MN	Upper Mississippi River mile marker 813.7 to 815.2.
25. 1 day—Sunday of Father's Day weekend.	Winona Steamboat Days/Winona Steamboat Days Fireworks.	Winona, MN	Upper Mississippi River mile marker 725.4 to 725.7.
26. 3 days—4th of July weekend.	Fair of St. Louis/Fair St. Louis	St. Louis, MO	Upper Mississippi River mile marker 179.2 to 180.0.
27. 1 day—Last weekend in June/First weekend in July.	Bellevue Heritage Days/Bellevue Heritage Days.	Bellevue, IA	Upper Mississippi River mile marker 556.0 to 556.5.
28. 1 day—4th of July weekend.	Main Street Parkway Association/Parkville 4th of July Fireworks.	Parkville, MO	Missouri River mile marker 378.0 to 377.5.
29. 1 day—4th of July weekend.	Hermann Chamber of Commerce/Hermann 4th of July.	Hermann, MO	Missouri River mile marker 097.0 to 098.0 (Missouri).
30. 1 day—4th of July weekend.	Grafton Chamber of Commerce/Grafton Chamber 4th of July Fireworks.	Grafton, IL	Upper Mississippi River mile marker 218 to 219.

TABLE 2 OF § 165.801—SECTOR UPPER MISSISSIPPI RIVER ANNUAL AND RECURRING SAFETY ZONES—Continued

Date	Sponsor/name	Sector Upper Mississippi River location	Safety zone
31. 1 day—4th of July weekend.	Salute to America Foundation, Inc./Salute to America.	Jefferson City, MO	Missouri River mile marker 143.5 to 143.0 (Missouri).
32. 2 days—2nd weekend in August.	Tug Committee/Great River Tug	Port Byron, IL	Upper Mississippi River mile marker 497.2 to 497.6 (Illinois).
33. 1 day—4th of July weekend.	City of Stillwater/St. Croix Events/Stillwater 4th of July.	Stillwater, MN	St. Croix River mile marker 022.9 to 023.5 (Minnesota).
34. 4 days—3rd week of July.	St. Croix Events/Lumberjack Days	Stillwater, MN	St. Croix River mile marker 022.9 to 023.5 (Minnesota).
35. 2 days—Weekend that precedes Labor Day Weekend.	Lake of the Ozarks Shootout, Inc./Lake of the Ozarks Shootout.	Lake of the Ozarks, MO	Lake of the Ozarks mile marker 032.5 to 034.5.
36. 2 days—1st weekend of September.	City of Keithsburg/Keithsburg Fireworks Display.	Keithsburg, IL	Upper Mississippi River mile marker 427.5 to 427.3.
37. 1 day—4th of July Week	City of East Moline/City of East Moline Fireworks.	East Moline, IL	Upper Mississippi River mile marker 489.9 to 490.2.
38. 2nd Weekend in August	Lansing Lion's Club/Lansing Fish Days Fireworks.	Lansing, IA	Upper Mississippi River mile marker 662.8–663.9.
39. 3rd Weekend in August	River Action/Floatzilla	Rock Island, Illinois	Upper Mississippi River mile marker 479.0–486.0.
40. 1 day—Weekend before Thanksgiving.	Main Street Parkway Association/Parkville Christmas on the River.	Parkville, MO	Missouri River mile marker 377.5 to 378.0.
41. 1 day—4th of July weekend.	City of Marquette/Marquette Independence Day Celebration.	Marquette, IA	Upper Mississippi River mile marker 634.2 to 635.7.
42. 1 day—1st Weekend in June.	St. Louis Brewers Guild Festival Fireworks.	St. Louis, MO	Upper Mississippi River mile marker 179.2–180
43. 1 day—4th Weekend in May.	Lumiere Place/Memorial Day Fireworks	St. Louis, MO	Upper Mississippi River mile marker 180–180.5
44. 1 day—1st Weekend in July.	Lumiere Place/4th of July Fireworks	St. Louis, MO	Upper Mississippi River mile marker 180–180.5
45. 1 day—1st Weekend in September.	Lumiere Place/Labor Day Fireworks	St. Louis, MO	Upper Mississippi River mile marker 180–180.5
46. 2 days—3rd Weekend in July.	Kentucky Drag Boat Association/Evansville, IL Drag Boat Races.	Evansville, IL	Kaskaskia River mile marker 9 to 11.

Dated: April 11, 2018.

Scott A. Stoermer,

Captain, U.S. Coast Guard, Captain of the Port Sector Upper Mississippi River.

[FR Doc. 2018–08013 Filed 4–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0332]

RIN 1625–AA00

Safety Zone; Lower Tchefuncte River, Madisonville, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone for certain navigable waters of the Tchefuncte River. This action is necessary to provide for the safety of life on these navigable waters near Madisonville, LA, during a fireworks display on July 4, 2018. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector New Orleans or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 17, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0332 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Howard Vacco, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2281, email *Howard.K.Vacco@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

On April 4, 2018, Geaux Pyro notified the Coast Guard that it would conduct a fireworks display from 7 p.m. through 7:20 p.m. on July 4, 2018, for a wedding celebration. The fireworks are to be launched from a barge on the Tchefuncte River, at approximate position 30°24′11.63″ N 090°09′17.39″ W, in front of the Madisonville Town Hall. Hazards from firework displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Sector New Orleans (COTP) has determined that potential hazards associated with the fireworks to be used in this display would be a safety concern for anyone within 100 yards of the launch barge.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 100-yard

radius of the launch barge before, during, and after the fireworks display. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish a safety zone from 6:45 p.m. through 7:45 p.m. on July 4, 2018. The safety zone would cover all navigable waters of the Tchefuncte River within 100-yards of a barge at approximate position 30°24′11.63″ N 090°09′17.39″ W, in front of the Madisonville Town Hall in Madisonville, LA. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled 7 p.m. to 7:20 p.m. fireworks display. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans.

Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67 or by telephone at (504) 365–2200. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size and duration of the safety zone. This proposed safety zone would only encompass a 100-yard radius of the Tchefuncte River for one hour on one evening. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the proposed rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rulemaking 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 rulemaking would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone lasting one hour that would prohibit entry within a 100-yard radius of a barge at approximate position of 30°24′11.63″ N 090°09′17.39″ W on the Tchefuncte River. Normally

such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

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

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

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0332 to read as follows:

§ 165.T08–0332 Safety Zone; Tchefuncte River, New Orleans, LA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Tchefuncte River, 100-yards around a barge at approximate position 30°24′11.63″ N 090°09′17.39″ W, in front of the Madisonville Town Hall in Madisonville, LA.

(b) *Effective period.* This section is effective from 6:45 p.m. through 7:45 p.m. on July 4, 2018.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless specifically authorized by the Captain of the Port Sector New Orleans (COTP) or designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans.

(2) Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67 or by telephone at (504) 365–2200.

(3) Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners of any changes in the planned schedule.

Dated: April 11, 2018.

Wayne R. Arguin,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2018–07909 Filed 4–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0331]

RIN 1625–AA00

Safety Zone; Lower Mississippi River, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone for certain navigable waters of the Mississippi River from mile marker (MM) 94 to MM 95 above Head of Passes. This action is necessary to provide for the safety of life on these navigable waters near Algiers Point, New Orleans, LA, during a fireworks display on June 30, 2018. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector New Orleans or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 17, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0331 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Commander Howard Vacco, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2281, email *Howard.K.Vacco@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

On April 4, 2018, AFX Pro, LLC, notified the Coast Guard that it would

be conducting a fireworks display from 10 p.m. through 10:45 p.m. on June 30, 2018, for a wedding celebration. The fireworks are to be launched from a barge in the Mississippi River at approximate mile marker (MM) 95.5 above Head of Passes near Algiers Point, New Orleans, LA. Hazards from firework displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Sector New Orleans (COTP) has determined that potential hazards associated with the fireworks to be used in this display would be a safety concern for anyone within a one-mile stretch of the river.

The purpose of this rulemaking is to ensure the safety of vessels on the navigable waters within a one-mile stretch of the river before, during, and after the fireworks display. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish a safety zone from 9:45 p.m. through 11 p.m. on June 30, 2018. The safety zone would cover all navigable waters of the Mississippi River above Head of Passes between mile markers (MM) 94 and 95. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled fireworks display. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans.

Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67 or by telephone at (504) 365–2200. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size and duration of the safety zone. This safety zone is for only one hour on a one-mile section of the waterway. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners (BNM) via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed 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 rulemaking 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 rulemaking would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland

Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone lasting one hour that would prohibit entry between mile marker 95 and mile marker 94 on the Lower Mississippi River above Head of Passes. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

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

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

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0331 to read as follows:

§ 165.T08–0331 Safety Zone; Lower Mississippi River, New Orleans, LA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Lower Mississippi River, New Orleans, LA from mile marker (MM) 94 to MM 95 above Head of Passes.

(b) *Effective period.* This section is effective from 9:45 p.m. through 11 p.m. on June 30, 2018.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port Sector New Orleans (COTP) or designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans.

(2) Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67 or by telephone at (504) 365–2200.

(3) Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners of any changes in the planned schedule.

Dated: April 11, 2018.

Wayne R. Arguin,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2018–07908 Filed 4–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[4500030115]

Endangered and Threatened Wildlife and Plants; 90-Day Findings for Two Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of petition findings and initiation of a status review.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce 90-day findings on two petitions to list, reclassify, or delist wildlife or plants under the Endangered Species Act of 1973, as amended (Act). Based on our review, we find that one petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted. Therefore, with the publication of this document, we announce that we plan to initiate a review of the status of that species to determine if the petitioned action is warranted. To ensure that this status review is comprehensive, we are requesting scientific and commercial data and other information regarding this species. Based on the status review, we will issue a 12-month finding on the petition, which will address whether or not the petitioned action is warranted, in accordance with the Act. We also find that one petition does not present substantial scientific or commercial information indicating that the petitioned action may be warranted. Therefore, we are not initiating a status review of this species in response to that petition. We refer to this finding as a ''not substantial'' petition finding.

DATES: These findings were made on April 17, 2018. As we commence work on the status review, we seek any new information concerning the status of, or threats to, the species or its habitat. Any information received during our work on the status review will be considered.

ADDRESSES:

Supporting documents: Summaries of the bases for the petition findings contained in this document are

available on *http://www.regulations.gov* under the appropriate docket number (see table under **SUPPLEMENTARY INFORMATION**). Supporting information in preparing these findings is available for public inspection, by appointment, during normal business hours by contacting the appropriate person, as specified in **FOR FURTHER INFORMATION CONTACT**.

Submitting information: If you have new scientific or commercial data or other information concerning the status of, or threats to, the species for which we made these petition findings, or their habitats, please submit that information by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter the appropriate docket number (see Table 1 under **SUPPLEMENTARY INFORMATION**). Then, click on the Search button. After finding the correct document, you may submit information by clicking on ''Comment Now!'' If your information will fit in the provided comment box, please use this feature of *http://www.regulations.gov,* as it is most compatible with our information review procedures. If you attach your information as a separate document, our preferred file format is Microsoft Word. If you attach multiple comments (such as form letters), our preferred format is a spreadsheet in Microsoft Excel.

(2) *By hard* copy: Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: [Insert appropriate docket number; see Table 1 under **SUPPLEMENTARY INFORMATION**], U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike; Falls Church, VA 22041–3803.

We request that you send information only by the methods described above. We will post all information we receive on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Request for Information for Status Reviews, below, for more information).

Not-substantial petition finding: A summary of the basis for the not-substantial petition finding contained in this document is available on *http://www.regulations.gov* under the appropriate docket number (see Table 2 under **SUPPLEMENTARY INFORMATION**). Supporting information in preparing this finding is available for public inspection, by appointment, during normal business hours by contacting the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**. If you have new information concerning the status of, or threats to, this species, or its habitat, please submit that information to the appropriate person.

FOR FURTHER INFORMATION CONTACT:

Common name	Contact person
Cape mountain zebra	Bridget Fahey, 703–358–2163; *bridget_fahey@fws.gov.*
Preble's meadow jumping mouse	Mike Thabault, 303–236–4210; *michael_thabault@fws.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations in title 50 of the Code of Federal Regulations (50 CFR part 424) set forth the procedures for adding a species to, or removing a species from, the Federal Lists of Endangered and Threatened Wildlife and Plants (Lists). Section 4(b)(3)(A) of the Act requires that we make a finding on whether a petition to add a species to the Lists (*i.e.,* ''list''), remove a species from the Lists (*i.e.,* ''delist''), or to change a listed species' status from endangered to threatened, or from threatened to endangered (*i.e.,* ''reclassify'') presents substantial scientific or commercial information indicating that the petitioned action may be warranted. To the maximum extent practicable, we are to make this finding within 90 days of our receipt of the petition and publish the finding promptly in the **Federal Register.**

Our regulations in the Code of Federal Regulations (CFR) establish that substantial scientific or commercial information with regard to a 90-day petition finding refers to ''credible scientific or commercial information in support of the petition's claims such that a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted'' (50 CFR 424.14(h)(1)(i)).

A species may be determined to be an endangered or threatened species because of one or more of the five factors described in section 4(a)(1) of the Act (16 U.S.C 1531 *et seq.*). The five factors are:

(a) The present or threatened destruction, modification, or curtailment of its habitat or range (Factor A);

(b) Overutilization for commercial, recreational, scientific, or educational purposes (Factor B);

(c) Disease or predation (Factor C);

(d) The inadequacy of existing regulatory mechanisms (Factor D); or

(e) Other natural or manmade factors affecting its continued existence (Factor E).

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself. However, the mere identification of any threat(s) may not be sufficient to compel a finding that the information in the petition is substantial information indicating that the petitioned action may be warranted. The information presented in the petition must include evidence sufficient to suggest that these threats may be affecting the species to the point that the species may meet the definition of an ''endangered'' species or ''threatened'' species under the Act.

If we find that a petition presents such information, our subsequent status review will evaluate all identified threats by considering the individual, population, and species-level effects, and the expected response by the species. We will evaluate individual threats and their expected effects on the species, then analyze the cumulative effect of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species—such as

any existing regulatory mechanisms or conservation efforts that may ameliorate threats. It is only after conducting this cumulative analysis of threats and the actions that may ameliorate them, and the expected effect on the species now and in the foreseeable future, that we can determine whether the species meets the definition of an ''endangered species'' or ''threatened species.''

If we find that a petition presents substantial scientific or commercial information, the Act requires us to promptly commence a review of the status of the species, and we will subsequently complete a status review in accordance with our prioritization methodology for 12-month findings (81 FR 49248; July 27, 2016).

Summaries of Petition Findings

The petition findings contained in this document are listed in the tables below and the bases for the findings, along with supporting information, are available on *http://www.regulations.gov* under the appropriate docket number.

TABLE 1—STATUS REVIEW

Common name	Docket No.	URL to docket on *http://www.regulations.gov.*
Cape mountain zebra	FWS–HQ–ES–2017–0100	*https://www.regulations.gov/docket?D=FWS-HQ-ES-2017-0100.*

TABLE 2—NOT-SUBSTANTIAL PETITION FINDING

Common name	Docket No.	URL to docket on *http://www.regulations.gov*
Preble's meadow jumping mouse	FWS–R6–ES–2017–0102	*https://www.regulations.gov/docket?D=FWS-R6-ES-2017-0102.*

Evaluation of a Petition To Delist the Cape Mountain Zebra or Reclassify the Subspecies as a Threatened Species Under the Act

Species and Range

Cape mountain zebra (*Equus zebra zebra*): South Africa (Eastern and Western Cape provinces).

Petition History

On May 10, 2017, we received a petition dated May 10, 2017, from Conservation Force and the Professional Hunters Association of South Africa requesting that we delist the Cape mountain zebra (*Equus zebra zebra*) or reclassify the subspecies from an endangered species to a threatened species under the Act. The petition clearly identified itself as such and included the requisite identification information for the petitioner, required at 50 CFR 424.14(c). This finding addresses the petition.

Finding

Based on our review of the petition and sources cited in the petition, we find that the petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted for the Cape mountain zebra due to the reduction or elimination of threats related to the following: Habitat availability (Factor A); commercial and recreational use (Factor B); disease and predation (Factor C); hybridization and inbreeding (Factor E); and the inadequacy of existing regulations with regards to a number of these threats (Factor D) (for information about these factors, see Background, above). However, during our status review, we will thoroughly evaluate all potential threats to the subspecies, including the extent to which any protections or other conservation efforts have reduced those threats. Thus, for this subspecies, the Service requests any information relevant to whether the subspecies falls within the definition of either ''endangered species'' under section 3(6) of the Act or ''threatened species'' under section 3(20) of the Act, including information on the five listing factors under section 4(a)(1) (see Request for Information for Status Reviews, below).

The basis for our finding on this petition, and other information regarding our review of the petition, can be found as an appendix at *http://www.regulations.gov* under Docket No. FWS–HQ–ES–2017–0100 under Supporting Documents.

Evaluation of a Petition To Delist the Preble's Meadow Jumping Mouse Under the Act

Species and Range

Preble's meadow jumping mouse (*Zapus hudsonius preblei*): Colorado and Wyoming.

Petition History

On March 30, 2017, we received a petition dated March 29, 2017, from Pacific Legal Foundation (on behalf of Dr. Rob Roy Ramey II; Center for Environmental Science, Accuracy and Reliability; Wyoming Stock Growers Association; Colorado Cattlemen's Association; Colorado Association of Home Builders; and Housing and Building Association of Colorado Springs), requesting that the Preble's meadow jumping mouse be delisted under the Act due to an error in taxonomic information. The petition clearly identified itself as such and included the requisite identification information for the petitioners, required at 50 CFR 424.14(c). This finding addresses the petition.

Finding

Based on our review of the petition and the source cited in the petition, we find that the petition presents no additional or new information that would support a taxonomic revision for the Preble's mouse or that would indicate that the subspecies is not a valid entity under the Act. Therefore, we find that the petition does not present substantial scientific or commercial information indicating that delisting the Preble's meadow jumping mouse may be warranted. Because the petition does not present substantial information indicating that delisting the Preble's meadow jumping mouse may be warranted, we are not initiating a status review of this species in response to this petition. However, we ask that the public submit to us any new information that becomes available concerning the status of, or threats to, this species or its habitat at any time (see *Not-substantial petition finding* under **ADDRESSES**, above).

The basis for our finding on this petition, and other information regarding our review of this petition, can be found as an appendix at *http://www.regulations.gov* under Docket No. FWS–R6–ES–2017–0102 under Supporting Documents.

Request for Information for Status Reviews

When we make a finding that a petition presents substantial

information indicating that listing, reclassification, or delisting of a species may be warranted, we are required to review the status of the species (a status review). For the status review to be complete and based on the best available scientific and commercial information, we request information on the species from governmental agencies, Native American Tribes, the scientific community, industry, and any other interested parties. We seek information on:

(1) The species' biology, range, and population trends, including:

(a) Habitat requirements;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns; and

(d) Historical and current population levels and current and projected trends.

(2) The five factors described in section 4(a)(1) of the Act (see Background, above) that are the basis for making a listing, reclassification, or delisting determination for a species under section 4(a) of the Act, including past and ongoing conservation measures that could decrease the extent to which one or more of the factors affect the species, its habitat, or both.

(3) The potential effects of climate change on the species and its habitat, and the extent to which it affects the habitat or range of the species.

Submissions merely stating support for or opposition to the actions under consideration without providing supporting information, although noted, will not be considered in making a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your information concerning the status review by one of the methods listed in **ADDRESSES**. If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If you submit a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this personal identifying information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

It is important to note that the standard for a 90-day finding differs from the Act's standard that applies to a status review to determine whether a petitioned action is warranted. In making a 90-day finding, we consider information in the petition and sources cited in the petition, as well as information that is readily available, and we evaluate merely whether that information constitutes ''substantial information'' indicating that the petitioned action ''may be warranted.'' In a 12-month finding, we must complete a thorough status review of the species and evaluate the ''best scientific and commercial data available'' to determine whether a petitioned action ''is warranted.'' Because the Act's standards for 90-day and 12-month findings are different, a substantial 90-day finding does not mean that the 12-month finding will result in a ''warranted'' finding.

Conclusion

On the basis of our evaluation of the information presented in the petitions under section 4(b)(3)(A) of the Act, we have determined that the petition summarized above for the Cape mountain zebra presents substantial scientific or commercial information indicating that the petitioned action may be warranted. We are, therefore, initiating a status review to determine whether the action is warranted under the Act. At the conclusion of the status review, we will issue a finding, in accordance with section 4(b)(3)(B) of the Act, as to whether the petitioned action is not warranted, warranted, or warranted but precluded by pending proposals to determine whether any species is an endangered species or a threatened species.

In addition, we have determined that the petition summarized above for the Preble's meadow jumping mouse does not present substantial scientific or commercial information indicating that the requested actions may be warranted. Therefore, we are not initiating a status review for this species.

Authors

The primary authors of this document are staff members of the Ecological Services Program, U.S. Fish and Wildlife Service.

Authority

The authority for these actions is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: February 23, 2018.

James W. Kurth,

Deputy Director, U.S. Fish and Wildlife Service, Exercising the Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2018–07707 Filed 4–16–18; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 83, No. 74
Tuesday, April 17, 2018

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

AGENCY FOR INTERNATIONAL DEVELOPMENT

Board for International Food and Agricultural Development; Notice of Meeting

Pursuant to the Federal Advisory Committee Act, notice is hereby given of the public meeting of the Board for International Food and Agricultural Development (BIFAD). The meeting will be held from 9:00 a.m. to 5:00 p.m. ET on Wednesday, May 9, 2018, at the Rotunda, Ronald Reagan Building and International Trade Center, 1300 Pennsylvania Ave. NW, Washington, DC. Participants may attend in person or join via livestream. The link to the global live stream as well as registration information can be found on BIFAD's home page: *http://www.usaid.gov/bifad.*

The central theme of this public meeting will be *Resilience Measurement and Analysis.* Dr. Brady Deaton, Acting BIFAD Chair, will preside over the public business meeting, which will begin promptly at 9:00 a.m. ET with opening remarks. At this meeting, the Board will address old and new business, including the presentation of the BIFAD Award for Scientific Excellence in an Innovation Lab. The purpose of this meeting is to share knowledge about theoretical and applied frameworks for resilience measurement and analysis and to identify opportunities to leverage U.S. university research capabilities to support resilience measurement and analysis. This event responds to priorities identified during the BIFAD meeting at the 2017 World Food Prize and the 2017 USAID Resilience Evidence Summit.

The meeting will be chaired by Dr. Brady Deaton, Acting BIFAD Chair and Chancellor Emeritus of the University of Missouri. The meeting will feature thought leaders on resilience measurement and analysis from USAID, academia and the practitioner community. Speakers include Dr. Greg Collins, Director of USAID's Center for Resilience and Dr. Mark Constas, Associate Professor at Cornell University, and Chair of the Food and Nutrition Security Resilience Measurement Technical Working Group.

At 4:00 p.m. ET, Acting Chairman Deaton will moderate a half-hour public comment period. At 5:00 p.m., Dr. Deaton will make closing remarks and adjourn the public meeting.

Those wishing to attend the meeting or obtain additional information about BIFAD should contact Clara Cohen, Designated Federal Officer for BIFAD in the Bureau for Food Security at USAID. Interested persons may write to her in care of the U.S. Agency for International Development, Ronald Reagan Building, Bureau for Food Security, 1300 Pennsylvania Avenue NW, Washington, DC, 20523–2110 or telephone her at (202) 712–0119.

Clara Cohen,

Designated Federal Officer, BIFAD, Bureau for Food Security, U.S. Agency for International Development.

[FR Doc. 2018–07968 Filed 4–16–18; 8:45 am]

BILLING CODE P

AGENCY FOR INTERNATIONAL DEVELOPMENT

Board for International Food and Agricultural Development; Notice of Meeting

Pursuant to the Federal Advisory Committee Act, notice is hereby given of the public meeting of the Board for International Food and Agricultural Development (BIFAD). The meeting will be held from 9:00 a.m. to 5:00 p.m. ET on Tuesday, May 8, 2018, at the Rotunda, Ronald Reagan Building and International Trade Center, 1300 Pennsylvania Ave. NW, Washington, DC. Participants may attend in person or join via livestream. The link to the global live stream as well as registration information can be found on BIFAD's home page: *http://www.usaid.gov/bifad.*

The central theme of this public meeting will be *Building an Evidence Base on Rural Youth Employment and Livelihoods.* Dr. Brady Deaton, Acting BIFAD Chair, will preside over the public business meeting, which will begin promptly at 9:00 a.m. ET with opening remarks. At this meeting, the Board will address old and new business and hear updates from USAID and the university community. The purpose of the meeting is to develop a shared understanding of rural labor markets and youth-specific constraints, discuss the evidence base on programs that aim to improve rural youth employment and livelihoods, outline cross-sectoral opportunities to support and empower youth to take advantage of agricultural system market opportunities, and identify knowledge gaps on which U.S. university research partners can generate evidence to address.

Following the opening remarks, the meeting will feature experts as well as panel discussions on the following topics:

- A Conceptual Framework on Youth and Agricultural Transformation;
- Framing the Evidence Base on Rural Youth Employment and Livelihoods;
- Youth Perspectives: Challenges and Opportunities in the Agricultural and Food Sectors;
- Youth Productivity: Technology, Mechanization, and Global Value Chains;
- Gender Considerations and Youth Employment;
- Research, Learning and USAID Programming: The Role of U.S. University Research Partners in Generating Evidence.

The meeting will be chaired by Dr. Brady Deaton, Acting BIFAD Chair and Chancellor Emeritus of the University of Missouri. Expert speakers include Dr. Louise Fox, USAID Chief Economist and Dr. David Tschirley, Food Security Group Co-Director, Michigan State University.

At 4:15 p.m. ET, Acting Chairman Deaton will moderate a half-hour public comment period. At 5:00 p.m., Dr. Deaton will make closing remarks and adjourn the public meeting.

Those wishing to attend the meeting or obtain additional information about BIFAD should contact Clara Cohen, Designated Federal Officer for BIFAD in the Bureau for Food Security at USAID. Interested persons may write to her in care of the U.S. Agency for International Development, Ronald Reagan Building, Bureau for Food Security, 1300 Pennsylvania Avenue NW, Washington,

DC, 20523–2110 or telephone her at (202) 712–0119.

Clara Cohen,

Designated Federal Officer, BIFAD, Bureau for Food Security, U.S. Agency for International Development.

[FR Doc. 2018–07966 Filed 4–16–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Intent To Grant Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the U.S. Department of Agriculture, Agricultural Research Service, intends to grant to Koppert B.V. of The Netherlands, an exclusive license to U.S. Patent Application Serial No. 14/854,120, ''STABLE FUNGAL BLASTOSPORES AND METHODS FOR THEIR PRODUCTION, STABILIZATION AND USE'', filed on September 15, 2015.

DATES: Comments must be received on or before May 17, 2018.

ADDRESSES: Send comments to: USDA, ARS, Office of Technology Transfer, 5601 Sunnyside Avenue, Rm. 4–1174, Beltsville, Maryland 20705–5131.

FOR FURTHER INFORMATION CONTACT: Brian T. Nakanishi of the Office of Technology Transfer at the Beltsville address given above; telephone: 301–504–5989.

SUPPLEMENTARY INFORMATION: The Federal Government's patent rights in this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license this invention as Koppert B.V. of The Netherlands has submitted a complete and sufficient application for a license. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Mojdeh Bahar,

Assistant Administrator.

[FR Doc. 2018–07977 Filed 4–16–18; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Settlement Pursuant to CERCLA; Libby Asbestos Site, Lincoln County, MT

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (CERCLA), notice is hereby given of an administrative settlement with W.R. Grace & Co. Conn. and the Kootenai Development Company (Grace) for the recovery of past response costs concerning Operable Unit 3 (OU3) of the Libby Asbestos Site, Lincoln County, Montana (the Site).

DATES: Comments must be submitted on or before May 17, 2018.

ADDRESSES: The proposed settlement is available for public inspection at the Libby Ranger District, Canoe Gulch Ranger Station, 12557 MT Hwy. 37, Libby, MT 59923, and at the offices of the USDA Forest Service, Northern Region, 26 Fort Missoula Road, Missoula, MT 59804. A copy of the proposed settlement may be obtained from Jeff Johnson at (208) 765–7313, Pamela Baltz (406) 283–7597, or from Babak Rastgoufard, USDA Office of the General Counsel at (406) 329–3061. Comments should reference the Libby Asbestos Site OU3, and should be addressed to Babak Rastgoufard, USDA Office of the General Counsel, 26 Fort Missoula Road, Missoula, MT 59804.

FOR FURTHER INFORMATION CONTACT: For technical information, contact Jeff Johnson, USDA Forest Service Northern Region, 3815 N Schreiber Way, Coeur d'Alene, ID 83815; phone (208) 765–7313 or Pamela Baltz, Kootenai National Forest, 12557 Hwy. 37, Libby, MT 59923; phone (406) 283–7597. For legal information, contact Babak Rastgoufard, USDA Office of the General Counsel, 26 Fort Missoula Road, Missoula, MT 59804; phone (406) 329–3061.

SUPPLEMENTARY INFORMATION: Pursuant to section 122(h)(1) of CERCLA, 42 U.S.C. 9622(h)(1), the settlement agreement resolves, in part, response costs incurred by the Forest Service at OU3. Under the settlement, Grace has agreed to pay the USDA Forest Service, Northern Region, $219,308 to reimburse it for certain response actions the USDA Forest Service, Northern Region, has undertaken at the Site. The settlement includes a covenant not to sue Grace for certain past costs pursuant to sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606 and 9607(a), with regard to the Site.

For thirty (30) days following the date of publication of this notice, the United States will receive written comments relating to the settlement. The United States will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The United States response to any comments received will be available for public inspection at the Libby Ranger District, Canoe Gulch Ranger Station, 12557 MT Hwy. 37, Libby, MT 59923, and at the offices of the USDA Forest Service, Northern Region, 26 Fort Missoula Road, Missoula, MT 59804.

Dated: March 14, 2018.

Chris French,

Associate Deputy Chief, National Forest System.

[FR Doc. 2018–07933 Filed 4–16–18; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Forest Products Removal Permits and Contracts

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested parties on the extension of a currently approved information collection, *Forest Products Removal Permits and Contracts.*

DATES: Comments must be received in writing on or before June 18, 2018 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Director, Forest & Rangeland Management and Vegetation Ecology, Forest Service, USDA, Mail Stop 1103, 1400 Independence Avenue SW, Washington DC 20250–1103.

Comments may also be submitted via facsimile to (703) 605–1575 or by email

to *forest_products_forms@fs.fed.us.* In addition, comments may be submitted via the world wide web/internet at: *http://www.regulations.gov.*

The public may inspect comments received at the Forest Service, Forest Management Staff Office, Third Floor SW Wing, 201 14th Street SW, Washington, DC 20250 during normal business hours. Visitors are encouraged to call ahead to (202) 205–1766 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Sharon Nygaard-Scott, Forest Management Staff, at (202) 205–1766. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Forest Products Removal Permits and Contracts.

OMB Number: 0596–0085.

Expiration Date of Approval: October 31, 2018.

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

Abstract: Under 16 U.S.C. 551 *Protection of National Forests; Rules and Regulations,* individuals and businesses wishing to remove forest products from National Forest System lands must request a permit. To obtain a permit, applicants must meet the criteria at 36 CFR 223.1, 223.2, and 223.5–223.13, which authorizes free use or sale of timber or forest products.

Under the *Food, Conservation, and Energy Act of 2008* (Pub. L. 110–246, 122 Stat. 1651) section 8105 *Forest Products for Traditional and Cultural Purposes* [hereinafter referred to as ''section 8105''], federally recognized Indian tribes may make a request for free use of trees, portions of trees, or forest products for traditional and cultural purposes, provided the use will not be for commercial purposes. Section 8105 has been codified in 25 U.S.C. chapter 32A *Cultural and Heritage Cooperation Authority,* section 3055 *Forest Products for Traditional and Cultural Purposes* (25 U.S.C. 3055). Additionally, Forest Service issued final implementation regulations, for section 8105, at 36 CFR 223.15 *Provision of Trees, Portions of Trees, or Forest Products to Indian Tribes for Traditional and Cultural Purposes.*

Indian tribes seeking products, under section 8105 authority, must make a request for free use, following the criteria at 36 CFR 223.15, which includes: ''Requests for trees, portions of trees, or forest products . . . must be submitted to the local Forest Service District Ranger's Office(s) in writing. Requests may be made: (1) Directly by a tribal official(s) who has been authorized by the Indian tribe to make such requests; or (2) By providing a copy of a formal resolution approved by the tribal council or other governing body of the Indian tribe.'' Note: there is no stated maximum free use limitation for products requested by Indian tribes, and there is no limitation to the number of requests that each federally recognized Indian tribe may make, under section 8105 authority. Should federally recognized Indian tribes seeking such use wish to obtain proof of possession, as may be required in some States, they could be issued a FS–2400–8 permit which allows use of timber or forest products at no charge (36 CFR 223.5–223.13).

Upon receiving a permit, the permittee must comply with the terms of the permit (36 CFR 261.6), which designates the forest products that can be harvested and under what conditions, such as limiting harvest to a designated area or permitting harvest of only specifically designated material. The collected information will help the Forest Service and the Bureau of Land Management (for form FS–2400–1) oversee the approval and use of forest products by the public.

When applying for forest product removal permits, applicants (depending on the products requested) would provide information needed to complete one of the following:

- FS–2400–1, *Forest Products Removal Permit and Cash Receipt,* is used to sell timber or forest products such as, but not limited to, fuelwood, Christmas trees, or pine cones (36 CFR 223.1, 223.2). The Bureau of Land Management identifies the FS–2400–1 as BLM–5450–24 (43 U.S.C 1201, 43 CFR 5420). This form would *not* be used to issue products requested by federally recognized Indian tribes under section 8105 authority.
- FS–2400–4/FS–2400–4ANF, *Forest Products Contract and Cash Receipt,* are used to sell timber products such as sawtimber or forest products such as, but not limited to, fuelwood, or posts and poles. These forms would *not* be used to issue products requested by federally recognized Indian tribes under section 8105 authority.
- FS–2400–8, *Forest Products Free Use Permit,* allows use of timber or forest products at no charge to the permittee (36 CFR 223.5–223.13). This form could be used to issue products requested by federally recognized Indian tribes under section 8105 authority.

Each form listed above implements different regulations and has different provisions for compliance, but collects similar information from the applicant for related purposes.

The Forest Service and the Bureau of Land Management will use the information collected on form FS–2400–1, to ensure identification of permittees in the field by agency personnel. The Forest Service will use the information collected on forms FS–2400–4/FS–2400–4ANF and/or FS–2400–8 to:

- Ensure that permittees obtaining free use of timber or forest products qualify for the free-use program.
- Ensure that permittees obtaining free use of timber or forest products, under 36 CFR 223.8, do not receive product value in excess of that allowed by regulations. However, as noted above for federally recognized Indian Tribe requests made under section 8105 authority, there is no stated maximum free use limitation (25 U.S.C. 3055).
- Ensure that applicants purchasing timber harvest or forest products permits non-competitively do not exceed the authorized limit in a fiscal year (16 U.S.C. 472(a)).
- Ensure identification of permittees, in the field, by Forest Service personnel.

Applicants may apply for more than one forest product permit or contract per year. For example, an applicant may obtain a free use permit for a timber product such as, but not limited to, pine cones (FS–2400–8) and still purchase fuelwood (FS–2400–1, and/or FS–2400–4/2400–4ANF). Additionally, as noted above, there is no limitation to the number of requests that each federally recognized Indian tribe may make under section 8105 authority (25 U.S.C. 3055).

Individuals and small business representatives usually request and apply for permits and contracts in person at the office issuing the permit. As noted above, Indian tribes seeking products under section 8105 authority must make a written request for free use, following the criteria at 36 CFR 223.15.

Applicants provide the following information, as applicable:

- Name,
- Address, and
- Personal identification number such as tax identification number, social security number, driver's license number, or other unique number identifying the applicant.

Agency personnel enter the information into a computerized database to use for subsequent requests by applicants for a forest product permit or contract. The information is printed on paper, which the applicant signs and dates. Agency personnel discuss the

terms and conditions of the permit or contract with the applicant.

The data gathered is not available from other sources. The collected data is used to ensure:

- Applicants for free use permits meet the criteria for free use of timber or forest products authorized by regulations at 36 CFR 223.5–223.13; and, for federally recognized Indian tribes under section 8105 authority, the criteria at 36 CFR 223.15;
- Applicants seeking to purchase and remove timber or forest products from Agency lands meet the criteria under which sale of timber or forest products is authorized by regulations at 36 CFR 223.80; and
- Permittees comply with regulations and terms of the permit at 36 CFR 261.6.

The collection of this information is necessary to ensure that applicants meet the requirements of the forest products program; those obtaining free-use permits for forest products qualify for the program; applicants purchasing non-competitive permits to harvest forest products do not exceed authorized limits; and that Federal Agency employees can identify permittees when in the field.

Estimate of Annual Burden: 5 minutes.

Type of Respondents: Individuals, small businesses, and, for requests made under section 8105 of *the Food, Conservation, and Energy Act of* 2008 (Pub. L. 110–246, 122 Stat. 1651), federally recognized Indian tribes.

Estimated Annual Number of Respondents: 192,224.

Estimated Annual Number of Responses per Respondent: 2.

Estimated Total Annual Burden on Respondents: 32,037.

Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (2) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request toward Office of Management and Budget approval.

Dated: March 28, 2018.

Glenn Casamassa,

Associate Deputy Chief, National Forest System.

[FR Doc. 2018–07934 Filed 4–16–18; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Oregon Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Oregon Advisory Committee (Committee) will hold a community forum on Tuesday, May 1, 2018, from 2:00 p.m.–5:00 p.m. PST for the purpose of hearing public testimony on civil rights concerns of human and labor trafficking in the sex, agriculture, and forestry industries and equal protection violations and discrimination based upon race, national origin, religion, sex, disability, and/or age of survivors. It will also examine the effectiveness of state and local agency programs for trafficking survivors.

DATES: The meeting will be held on Tuesday, May 1, 2018, at 2:00 p.m. PST to 5:00 p.m. PST.

Location: Portland Community College, Sylvania Campus, CC Building, Room 233, 12000 SW 49th Avenue, Portland, OR 97280.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: Members of the public are entitled to make comments during the open comment periods. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://facadatabase.gov/committee/meetings.aspx?cid=270.* Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

Opening Remarks (2:00–2:10 p.m.)

Panel—Sex Trafficking (2:10–3:50 p.m.)

- Senator Kathleen Taylor, District 21
- Chanpone Sinlapasai, Attorney, Marandas Sinlapasai
- Natalie Weaver, Collaboration Specialist focus on Sex Trafficking, Multnomah County, Department of Community Justice
- Desireé Coyote, Confederated Tribes of Umatilla Indian Reservation, Family Violence Services
- Robin Miller, Mentor and Survivor, Janus Youth Programs
- Cristin Casey, Chief Prosecutor, Bureau of Labor and Industries

Open Public Comment (4:00–4:55 p.m.)

Dated: April 11, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–07897 Filed 4–16–18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Rhode Island Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meetings.

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 planning meeting of the Rhode Island State Advisory Committee to the Commission will convene by conference call, on Tuesday, May 1, 2018 at 11:00 a.m. (EDT). The purpose of the meeting is to review and vote on a work product generated at the Committee's briefing on Predatory

Lending. The Committee will also discuss next steps for the predatory lending project.

DATES: Tuesday, May 1, 2018, at 11:00 a.m. (EDT).

Public Call-In Information: Conference call number: 1–888–334–3020 and conference call ID: 8405258.

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 number: 1–888–334–3020 and conference call ID: 8405258. Please be advised that before placing them into the conference call, the conference call operator may 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 telephone number herein.

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 number:1–888–334–3020 and conference call ID: 8405258.

Members of the public are invited to 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, 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/committee/meetings.aspx?cid=272;* 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 number, email or street address.

Agenda: Tuesday, April 3, 2018 at 11:00 a.m. (EDT)

I. Welcome and Introductions
  Rollcall
II. Planning Meeting
  Review of Work Product on Predatory Lending
  Vote on Predatory Lending Work Product
  Discuss Next Steps for Predatory Lending Project
III. Other Discussion
IV. Open Comment
V. Adjournment

Dated: April 12, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–08008 Filed 4–16–18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Oregon Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Oregon Advisory Committee (Committee) will hold a community forum on Wednesday, May 2, 2018, from 2:00 p.m.–5:00 p.m. PST for the purpose of hearing public testimony on civil rights concerns of human and labor trafficking in the sex, agriculture, and forestry industries and equal protection violations and discrimination based upon race, national origin, religion, sex, disability, and/or age of survivors. It will also examine the effectiveness of state and local agency programs for trafficking survivors.

DATES: The meeting will be held on Wednesday, May 2, 2018, at 2:00 p.m. PST to 5:00 p.m. PST.

ADDRESSES: Chemeketa Woodburn Center, Room 110, 120 E Lincoln Street, Woodburn, OR 97071.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: Members of the public are entitled to make comments during the open comment periods. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://facadatabase.gov/committee/meetings.aspx?cid=270.* Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

Opening Remarks (2:00–2:10 p.m.)
Panel—Labor Trafficking in the Agriculture and Forestry Industries (2:10–3:10 p.m.)
- Reyna Lopez, Executive Director, Pineros y Campesinos Unidos del Noroeste
- Carl Wilmsen, Executive Director, Northwest Forest Worker Center
- Joel Iboa, Chair, Governor's Environmental Justice Task Force

Open Public Comment (3:20 p.m.–4:55 p.m.)

Dated: April 11, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–07898 Filed 4–16–18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the West Virginia 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 meeting of the West Virginia Advisory Committee to the Commission will convene by conference call at 12:00 p.m. (EST) on Friday, May 4, 2018. The purpose of the meeting is hear presentations from a panel of experts who will provide a

national perspective on the impact a felony conviction/record has on persons access to employment, housing occupational licenses and public benefits.

DATES: Friday, May 4, 2018, at 12:00 p.m. (EDT).

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

SUPPLEMENTARY INFORMATION: Public Call-In Information: Conference call-in number: 1–800–474–8920 and conference call number: 8310490.

Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 1–800–474–8920 and conference call number: 8310490. Please be advised that before being placed 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 may incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charges 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 1–888–364–3109 and providing the operator with the toll-free conference call-in number: 1–800–474–8920 and conference call number: 8310490.

Members of the public are entitled to 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, or emailed to Corrine Sanders 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://database.faca.gov/committee/meetings.aspx?cid=279,* 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: Friday, May 4, 2018, at 12:00 p.m. (EDT)

I. Rollcall
II. Welcome and Introductions
III. Panel Presentation
IV. Adjourn

Dated: April 11, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–07896 Filed 4–16–18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the District of Columbia Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of monthly planning 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 planning meeting of the District of Columbia Advisory Committee to the Commission will convene at 11:30 a.m. (EDT) Tuesday, May 8, 2018 at the offices of the U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue NW, Suite 1150, Washington, DC 20425. The purpose of the planning meeting is to continue project planning. This fall the Committee will conduct a briefing meeting on its civil rights project, which examines the treatment of homeless persons that get swept up in the DC criminal justice system, including a review of the DC Mental Health Court.

DATES: May 8, 2018 at 11:30 a.m. (EDT).

ADDRESSES: 1331 Pennsylvania Avenue NW, Suite 1150, Washington, DC 20425.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Persons with accessibility needs should contact the Eastern Regional Office no later than 10 working days before the scheduled meeting by sending an email to the following email address at *ero@usccr.gov.*

Members of the public are entitled to submit written comments. The comments must be received in the regional office by Friday, June 8, 2018. Comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue Suite 1150, Washington, DC 20425 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 *http://facadatabase.gov/committee/meetings.aspx?cid=241;* 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 meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone numbers, email or street address.

Agenda

Tuesday, May 8, 2018 at 11:30 a.m.

I. Rollcall
II. Welcome and Introductions
III. Discuss Project Planning
IV. Other Business
V. Adjourn

Dated: April 11, 2018.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2018–07895 Filed 4–16–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–968]

Aluminum Extrusions From the People's Republic of China: Correction of Notification of Rescission, in Part; 2016

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

FOR FURTHER INFORMATION CONTACT: Davina Friedmann or Tom Bellhouse, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0698 or (202) 482–2057, respectively.

SUPPLEMENTARY INFORMATION: On March 15, 2018, the Department of Commerce (Commerce) published the *Preliminary Results* in the 2016 countervailing duty administrative review of aluminum extrusions from the People's Republic of

China.[1] In that notice, Commerce incorrectly listed Guangdong Xin Wei Aluminum Products Co., Ltd. among the companies for which it was rescinding the administrative review.[2] Commerce intended for Guangdong Xin Wei Aluminum Products Co., Ltd. to only be listed in the ''Intent to Rescind Administrative Review, In Part'' section of the *Preliminary Results*, rather than in Appendix II.[3]

This notice serves as a correction that we have not rescinded this administrative review with respect to Guangdong Xin Wei Aluminum Products Co., Ltd. Rather, we preliminarily intend to rescind the review with respect to Guangdong Xin Wei Aluminum Products Co., Ltd., because there is no evidence on the record to indicate that it had entries of subject merchandise during the period of review. As stated in the Preliminary Results, a final decision regarding whether to rescind the review of this company will be issued with the final results of review.

Dated: April 11, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–07992 Filed 4–16–18; 8:45 am]

BILLING CODE 3510–DS–P1

[1] *See Aluminum Extrusions from the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, Rescission of Review, in Part, and Intent to Rescind, in Part; 2016*, 83 FR 11501 (March 15, 2018) (*Preliminary Results*),

[2] *Id.*, 83 FR at Appendix II.

[3] *Id.*, 83 FR at 11502.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–912]

Certain New Pneumatic Off-the-Road Tires From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and New Shipper Review; 2015–2016

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

SUMMARY: The Department of Commerce (Commerce) determines that Weihai Zhongwei Rubber Co., Ltd., a manufacturer/exporter of certain new pneumatic off-the-road tires (OTR tires) from the People's Republic of China (China), sold subject merchandise in the United States at prices below normal value during the period of review (POR). Additionally, we determine that Guizhou Tyre Co., Ltd. and its affiliate are ineligible for separate rate status. Finally, the new shipper review with respect to The Carlstar Group LLC, the producer Carlisle (Meizhou) Rubber Manufacturing Co., Ltd., and its affiliated exporter CTP HK has been rescinded.

DATES: Applicable: April 17, 2018.

FOR FURTHER INFORMATION CONTACT: Alex Rosen AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–7814.

SUPPLEMENTARY INFORMATION:

Background

On October 10, 2017, Commerce published its *Preliminary Results* of the antidumping duty administrative review (AR) and new shipper review (NSR).[1] On December 11, 2017, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), Commerce extended the period for issuing the final results of this review by 60 days, to April 9, 2018.[2] On January 23, 2018, Commerce exercised its discretion to toll all deadlines affected by for the duration of the closure of the Federal Government from January 20 through 22, 2018. As a result, the period for issuing the final results of this review by Commerce has been extended to April 11, 2018.[3]

In accordance with 19 CFR 351.309, we invited interested parties to comment on the *Preliminary Results,* as well as information provided to the record subsequently. We received case briefs from The United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO–CLC (the petitioners), the mandatory AR respondents Weihai Zhongwei Rubber Co., Ltd. (Zhongwei) and GTC,[4] interested party Valmont Industries Inc., and NSR respondent Carlstar.[5] We received rebuttal briefs from the petitioners, Zhongwei, and Carlstar. For a further discussion of the events that occurred in this investigation subsequent to the *Preliminary Results, see* the Issues and Decision Memorandum.[6]

Scope of the Order

The merchandise covered by this order includes new pneumatic tires designed for off-the-road and off-highway use, subject to certain exceptions. The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4011.20.10.25, 4011.20.10.35, 4011.20.50.30, 4011.20.50.50, 4011.61.00.00, 4011.62.00.00, 4011.63.00.00, 4011.69.00.00, 4011.92.00.00, 4011.93.40.00, 4011.93.80.00, 4011.94.40.00, and 4011.94.80.00. The HTSUS subheadings are provided for convenience and customs purposes only; the written product description of the scope of the order is dispositive. For a complete description of the scope of the order, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs filed by parties in this review are addressed in the Issues and Decision Memorandum, which is hereby

[1] *See Certain New Pneumatic Off-the-Road Tires From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Rescission of New Shipper Review; 2015–2016,* 82 FR 46965 (October 10, 2017) (*Preliminary Results*) and accompanying ''Decision Memorandum for Preliminary Results of the Antidumping Duty Administrative Review and Preliminary Recession of New Shipper Review: Certain New Pneumatic Off-the-Road Tires from the People's Republic of China; 2015–2016,'' dated October 2, 2017 (Preliminary Decision Memorandum).

[2] *See* memorandum, ''Certain New Pneumatic Off-the-Road Tires from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrative Review and New Shipper Review; 2015–2016,'' dated December 11, 2017.

[3] *See* memorandum, ''Deadlines Affected by the Shutdown of the Federal Government'' (Tolling Memorandum), dated January 23, 2018. All deadlines in this segment of the proceeding have been extended by 3 days.

[4] In the initial investigation, Commerce collapsed Guizhou Tyre Co., Ltd. and Guizhou Tyre Import and Export Corporation (GTCIE) into a single entity, *see Certain New Pneumatic Off-The-Road Tires From the People's Republic of China; Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 73 FR 9278, 9283 (February 20, 2008), unchanged in *Certain New Pneumatic Off-The-Road Tires from the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances,* 73 FR 40485 (July 15, 2008). This decision is unchallenged in the instant review; thus, Commerce continues to treat GTC and GTCIE as a single entity (collectively, GTC).

[5] The NSR was requested by Carlstar Group LLC (formerly dba CTP Transportation Products) (Carlstar Group), a U.S. producer, importer and seller of subject merchandise; concerning merchandise produced by Carlisle (Meizhou) Rubber Manufacturing Co., Ltd. (Carlisle Meizhou), its affiliated producer of OTR tires from China, and exported by CTP Distribution (HK) Limited (CTP HK), an affiliated trading company located in Hong Kong (collectively, Carlstar).

[6] *See* memorandum, ''Issues and Decision Memorandum for Final Results of Antidumping Duty Administrative Review and New Shipper Review: Certain New Pneumatic Off-the-Road Tires from the People's Republic of China; 2015–2016,'' adopted by and dated concurrently with this notice (Issues and Decision Memorandum).

adopted by this notice. A list of the issues that parties raised and to which we responded in the Issues and Decision Memorandum is attached in the Appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and it is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and electronic version of the Issues and Decision Memorandum are identical in content.

Recession of the New Shipper Review

In accordance with 19 CFR 351.214(c), an exporter or producer may request an NSR within one year of the date on which subject merchandise was first entered, or withdrawn from warehouse, for consumption, or, if the exporter or producer cannot establish the date of the first entry, then the date on which it first shipped the merchandise for export to the United States.

As discussed in the Issues and Decision Memorandum and NSR Rescission Memorandum, Commerce finds that Carlstar's request for a new shipper review was not timely filed within one year of the date the subject merchandise produced and exported by Carlstar's predecessor was first entered into the United States, pursuant to 19 CFR 351.214(c).[7] As a result, we determine that Carlstar's request did not meet the requirements of 19 CFR 351.214(c), and are rescinding the new shipper review for Carlstar. Because much of the factual information used in our analysis involves business proprietary information, a full discussion of the basis for our determination is set forth in the NSR Rescission Memorandum.

Separate Rates

In the *Preliminary Results,* we determined that Zhongwei, as well as two separate rate applicants, Qingdao Qihang Tyre Co. Ltd. (Qihang) and Shandong Zhentai Group Co., Ltd. (Zhentai), were eligible for separate-rate status. We also preliminarily determined that GTC, as well as separate rate applicant Cheng Shin Rubber Industry Ltd. (Cheng Shin), and non-responsive respondent Qingdao Milestone Tyres Co. Ltd. (Milestone), were not eligible for a separate rate, and are, thus, part of the China-wide entity.[8] We received no information since the issuance of the *Preliminary Results* that provides a basis for reconsidering these determinations, therefore, for the final results we continue to find that Zhongwei, Qihang, and Zhentai are eligible for separate rates and that GTC, Cheng Shin, and Milestone are ineligible for separate rates. Additionally, as a result of Commerce's rescission of the new shipper review with respect to Carlstar, and because Carlstar did not submit a separate rate application in the administrative review, it has not been granted a separate rate. For further discussion, *see* Issues and Decision Memorandum at Comments 1 and 2.

Rate for Non-Individually-Examined Separate Rate Companies

The statute and Commerce's regulations do not address the establishment of a rate to be assigned to respondents not selected for individual examination when Commerce limits its examination of companies subject to the administrative review pursuant to section 777A(c)(2)(B) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for respondents not individually examined in an administrative review. Section 735(c)(5)(A) of the Act articulates a preference for not calculating an all-others rate using rates which are zero, *de minimis,* or based entirely on facts available.[9] Accordingly, Commerce's usual practice has been to determine the dumping margin for companies not individually examined by averaging the weighted-average dumping margins for the individually examined respondents, excluding rates that are zero, *de minimis,* or based entirely on facts available.[10] In this review, we have calculated a weighted-average dumping margin for Zhongwei that is above *de minimis* and not based entirely on facts available. Therefore, consistent with Commerce's practice, we have assigned to Qihang and Zhentai the weighted-average dumping margin calculated for Zhongwei as the separate rate for this review.

Changes Since the Preliminary Results

Based on an analysis of the comments received, we made certain calculation changes and revisions to the valuation of certain factors of production since the *Preliminary Results* with respect to Zhongwei's margin calculation. For further details on the changes made since the *Preliminary Results, see* the Issues and Decision Memorandum.[11]

In light of changes made since the *Preliminary Results* which altered Zhongwei's margin, we have updated the separate rate that assigned to Qihang and Zhentai.

Final Results of Review

As a result of this administrative review, we determine that the following weighted-average dumping margins exist for the period September 1, 2015, through August 31, 2016:

Exporter	Weighted-average dumping margin (percent)
Weihai Zhongwei Rubber Co., Ltd	11.87
Qingdao Qihang Tyre Co. Ltd	11.87
Shandong Zhentai Group Co., Ltd	11.87

Additionally, as in the *Preliminary Results,* Commerce determines that GTC, Cheng Shin, and Milestone, are part of the China-wide entity.

[7] *See* memorandum, ''New Pneumatic Off-the-Road Tires from the People's Republic of China: Final Analysis of Comments Regarding the Determination to Rescind the New Shipper Review,'' dated concurrently with this memorandum (NSR Final Rescission Memorandum).

[8] *See Preliminary Results,* 82 FR at 46966, and accompanying PDM at the ''Separate Rate Analysis'' section.

[9] *See Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews and Rescission of Reviews in Part,* 73 FR 52823, 52824 (September 11, 2008), and accompanying Issues and Decision Memorandum at Comment 16.

[10] *See, e.g., Preliminary Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 71 FR 77373, 77377 (December 26, 2006), unchanged in *Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 72 FR 19690 (April 19, 2007).

[11] *See also,* memorandum, ''Final Results of the 2015–2016 Administrative Review of the Antidumping Duty Order on Certain New Pneumatic Off-The-Road Tires from the People's Republic of China: Surrogate Value Memorandum,'' dated concurrently with this notice, and memorandum, ''2015–2016 Administrative Review of the Antidumping Duty Order on Certain New Pneumatic Off-the-Road Tires from the People's Republic of China: Analysis of the Final Results Margin Calculation for Weihai Zhongwei Rubber Co., Ltd.,'' dated concurrently with this notice.

Disclosure

We intend to disclose the calculations performed regarding these final results within five days of the date of publication of this notice to parties in this proceeding, in accordance with 19 CFR 351.224(b).

Assessment Rates

Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1).[12] Commerce intends to issue assessment instructions directly to CBP 15 days after the date of publication of these final results of administrative review.

For Zhongwei, Commerce will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of sales, in accordance with 19 CFR 351.212(b)(1). For customers or importers of Zhongwei for which we do not have entered values, we calculated importer- (or customer-) specific antidumping duty assessment amounts based on the ratio of the total amount of dumping duties calculated for the examined sales of subject merchandise to the total sales quantity of those same sales.[13] For customers or importers of Zhongwei for which we received entered-value information, we have calculated importer- (or customer-) specific antidumping duty assessment rates based on importer- (or customer-) specific *ad valorem* rates.[14] Where an importer- or (customer-) specific *ad valorem* rate is greater than *de minimis,* Commerce will instruct CBP to collect the appropriate duties at the time of liquidation.[15]

For the non-examined separate rate companies, we will instruct CBP to liquidate all appropriate entries at 11.87 percent, which is equal to the weighted-average dumping margin assigned to Zhongwei.

For those entities that are subject to this review that Commerce has determined are part of the China-wide entity (*i.e.,* GTC, Cheng Shin and Milestone), we will instruct CBP to liquidate all appropriate entries at the China-wide rate of 105.31 percent.[16] Pursuant to a refinement in Commerce's non-market economy (NME) practice, for entries that were not reported in the U.S. sales databases submitted by companies individually examined during this review, Commerce will instruct CBP to liquidate such entries at the China-wide rate.[17] In addition, if Commerce determines that an exporter under review had no shipments of subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the China-wide rate.

Because we are rescinding the new shipper review of Carlstar, we have not made a determination as to whether Carlstar qualifies for a separate rate. Therefore, Carlstar will remain part of the China-wide entity and, accordingly, any entries covered by this new shipper review will be assessed at the China-wide rate.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be equal to the weighted-average dumping margin identified in the ''Final Results'' section of this notice, above; (2) for previously investigated or reviewed Chinese and non-Chinese exporters that are not under review in this segment of the proceeding but that received a separate rate in a previous segment, the cash deposit rate will continue to be the exporter-specific rate (or exporter-producer chain rate) published for the most recently completed segment of this proceeding in which the exporter was reviewed; (3) for all Chinese exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the China-wide rate of 105.31 percent; and (4) for all non-China exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the China exporter(s) that supplied that non-China exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Because we did not calculate a dumping margin for Carlstar or grant Carlstar a separate rate in this new shipper review, as noted above, we find that Carlstar continues to be part of the China-wide entity. The cash deposit rate for the China-wide entity is 105.31 percent. These cash deposit requirements shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of the antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these final results of administrative review in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: April 11, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Changes since the *Preliminary Results*
V. Discussion of the Issues
Comment 1: Carlstar's Eligibility for a New Shipper Review (NSR)
Comment 2: GTC's Separate Rate Eligibility
A. The Statutory Authority to Issue a Country-Wide Rate
B. The Presumption of Chinese Government Control

[12] *See Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8103 (February 14, 2012) (*NME Antidumping Proceedings*).

[13] *See* 19 CFR 351.212(b)(1).

[14] *Id.*

[15] *See* 19 CFR 351.212(b)(1).

[16] The China-wide rate was determined in *Certain New Pneumatic Off-the-Road Tires from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2012–2013,* 80 FR 20197 (April 15, 2015).

[17] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

C. The Government Control of GTC's Export Activities
D. WTO Obligations
E. A New China-Wide Rate Applicable to GTC
F. Adjustments for Domestic and Export Subsidies Found in the Parallel CVD Review
Comment 3: Surrogate Value for Mixed Rubber
Comment 4: Overhead and Selling, General and Administrative Expenses (SG&A) Ratios Used to Calculate Zhongwei's Margin
Comment 5: CVD Rates Used to Calculate Double-Remedies Adjustment for Zhongwei
Comment 6: Irrecoverable Value-Added Tax (VAT) Rate for Zhongwei
VI. Recommendation

[FR Doc. 2018–07991 Filed 4–16–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–830]

Carbon and Certain Alloy Steel Wire Rod From Mexico: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2015–2016

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

SUMMARY: The Department of Commerce (Commerce) finds that Deacero S.A.P.I. de C.V. (Deacero), a producer and exporter of carbon and certain alloy steel wire rod (wire rod) from Mexico, made sales of subject merchandise at less than normal value (NV) during the period of review (POR), October 1, 2015, through September 30, 2016. We also find that ArcelorMittal las Truchas, S.A. de C.V. (AMLT) made no shipments of subject merchandise during the POR.

DATES: Applicable April 17, 2018.

FOR FURTHER INFORMATION CONTACT: Keith Haynes, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5139.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the preliminary results of this administrative review of wire rod from Mexico on November 8, 2017.[1] We invited interested parties to comment on the *Preliminary Results.* On December 8, 2017, Commerce received timely filed case briefs from Deacero, and Nucor Corporation (Nucor).[2] On December 20, 2017, Commerce received timely filed rebuttal briefs from both Deacero and Nucor.

Commerce has exercised its discretion to toll all deadlines affected by the duration of the closure of the Federal Government from January 20 through 22, 2018.[3] Additionally, on February 27, 2018, Commerce postponed the final results of this review by 30 days until April 11, 2018.[4]

Based on an analysis of the comments received, Commerce has made changes to the calculated weighted-average dumping margin determined for Deacero. Commerce has listed the final calculated weighted-average dumping margin in the ''Final Results of Administrative Review'' section below.

Scope of the Order [5]

The product covered by the order is wire rod, in coils, of approximately round cross section, 5.00 mm or more, but less than 19.00 mm, in solid cross-sectional diameter.[6] The subject merchandise is currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 7213.91.3000, 7213.91.3010, 7213.91.3011, 7213.91.3015, 7213.91.3020, 7213.91.3090, 7213.91.3091, 7213.91.3092, 7213.91.3093, 7213.91.4500, 7213.91.4510, 7213.91.4590, 7213.91.6000, 7213.91.6010, 7213.91.6090, 7213.99.0030, 7213.99.0031, 7213.99.0038, 7213.99.0090, 7227.20.0000, 7227.20.0010, 7227.20.0020, 7227.20.0030, 7227.20.0080, 7227.20.0090, 7227.20.0095, 7227.90.6010, 7227.90.6020, 7227.90.6030, 7227.90.6035, 7227.90.6050, 7227.90.6051, 7227.90.6053, 7227.90.6058, 7227.90.6059, 7227.90.6080, and 7227.90.6085. The HTSUS subheadings are provided for convenience and customs purposes only; the written product description remains dispositive.

Analysis of Comments Received

Commerce has addressed the issues raised by Deacero and Nucor in their case and rebuttal briefs in the Issues and Decision Memorandum. Commerce has identified and listed these issues in the Appendix to this notice. Because the Issues and Decision Memorandum is a public document, parties can find a complete discussion of these issues and the corresponding recommendations filed electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and in the Central Records Unit, room B8024 of the main Department of Commerce building. Additionally, parties can access a complete version of the Issues and Decision Memorandum directly on the internet at *http://trade.gov/enforcement/frn/index.html.* The signed Issues and Decision Memorandum and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on the case brief and rebuttal comments received from Deacero and Nucor, we made changes to our rate calculation for Deacero. For a discussion of these issues, *see* the Issues and Decision Memorandum.

Final Determination of No Shipments

In the *Preliminary Results,* we preliminarily found that AMLT had no

[1] *See Carbon and Certain Alloy Steel Wire Rod from Mexico: Preliminary Results and Preliminary Determination of No Shipments; 2015–2016,* 82 FR 51819 (November 8, 2017) (*Preliminary Results*).

[2] *See* Deacero's Case Brief, ''Carbon and Certain Alloy Steel Wire Rod from Mexico—Case Brief,'' dated December 8, 2017 (Deacero's Case Brief); the Nucor's Case Brief, ''Carbon and Certain Alloy Steel Wire Rod from Mexico: Case Brief,'' dated December 8, 2017 (Nucor's Case Brief).

[3] *See* Memorandum for The Record from Christian Marsh, Deputy Assistant Secretary for Enforcement and Compliance, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Shutdown of the Federal Government'' (Tolling Memorandum), dated January 23, 2018. All deadlines in this segment of the proceeding affected by the closure of the Federal Government have been extended by 3 days.

[4] *See* Commerce Letter re: Carbon and Certain Alloy Steel Wire Rod from Mexico: Extension of Deadline for Final Results of Antidumping Duty Administrative Review; 2015–2016, dated February 27, 2018.

[5] For the full text of the scope of the order, *see* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2015–2016 Antidumping Duty Administrative Review: Carbon and Certain Alloy Steel Wire Rod from Mexico,'' dated concurrently with this determination and hereby adopted by this notice (Issues and Decision Memorandum).

[6] On October 1, 2012, Commerce determined that Deacero's shipments to the United States of narrow gauge wire rod (4.75 mm to 5.00 mm) (narrow gauge wire rod) constitute merchandise altered in form or appearance in such minor respects that it should be included within the scope of the order on wire rod from Mexico. *See Carbon and Certain Alloy Steel Wire Rod from Mexico: Affirmative Final Determination of Circumvention of the Antidumping Order,* 77 FR 59892 (October 1, 2012) and accompanying Issues and Decision Memorandum. The U.S. Court of Appeals for the Federal Circuit upheld this determination. *See Deacero S.A. de C.V.* v. *United States,* 817 F.3d 1332, 1339 (Fed. Cir. 2016). Because there were no changes to the facts which supported that decision since that determination, we continue to find Deacero's narrow gauge wire rod (4.75 mm to 5.00 mm) subject merchandise.

shipments during the POR.[7] Because there has not been any contradictory information added to the record of this review since the *Preliminary Results,* based on record evidence, Commerce continues to find that AMLT did not ship subject merchandise during the POR. Accordingly, consistent with Commerce's practice, we intend to instruct U.S. Customs and Border Protection (CBP) to liquidate any existing entries of subject merchandise made during the POR that were produced by AMLT, but exported by other parties without their own rate, at the all-others rate effective during the POR.[8]

Final Results of Administrative Review

Commerce finds that the following estimated weighted-average dumping margin exists during the POR, as referenced below:

Producer/exporter	Weighted-average dumping margin (percent)
Deacero S.A.P.I. de C.V	12.57

Assessment and Cash Deposit Requirements

In accordance with 19 CFR 351.212(b)(1), Commerce intends to issue appropriate instructions to CBP 41 days after publication of the final results of this review.[9]

For Deacero, because its weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent), Commerce has calculated importer-specific antidumping duty assessment rates. We calculated importer-specific *ad valorem* antidumping duty assessment rates by aggregating the total amount of dumping calculated for the examined sales of each importer and dividing each of these amounts by the total entered value associated with those sales. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review where an importer-specific assessment rate is not zero or de minimis. Pursuant to 19 CFR 351.106(c)(2), we will instruct CBP to liquidate without regard to antidumping duties any entries for which the importer-specific assessment rate is zero or *de minimis.*

As noted in the ''Final Determination of No Shipments'' section, above, Commerce will instruct CBP to liquidate any existing entries of merchandise produced by AMLT but exported by other parties, at the rate for the intermediate reseller, if available, or at the all-others rate.

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication of the final results of this administrative review, as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for Deacero will be the rate established in the final results of this administrative review; (2) for merchandise exported by producers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the producer is, the cash deposit rate will be the rate established for the most recent period for the producer of the merchandise; and (4) the cash deposit rate for all other producer or exporters will continue to be 20.11 percent, the all-others rate established in the investigation.[10] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 11, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Analysis of Comments
  Comment 1: Whether Deacero's Reported Billet Cost Data Are Reliable
  Comment 2: Whether to Cap Deacero's Freight Revenue by its Freight Cost
  Comment 3: Whether to Rely on a Different Cost of Production (COP) Database
  Comment 4: Treatment of Certain Mixed Currency Variables Within the Margin Program
  Comment 5: Treatment of Certain Commissions Within the Margin Program
V. Recommendation

[FR Doc. 2018–07993 Filed 4–16–18; 8:45 am]

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[7] *See Preliminary Results,* 82 FR at 51819–20.

[8] *See, e.g., Magnesium Metal from the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review,* 75 FR 26922, 26923 (May 13, 2010), unchanged in *Magnesium Metal from the Russian Federation: Final Results of Antidumping Duty Administrative Review,* 75 FR 56989 (September 17, 2010). *See also Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[9] *See* 19 CFR 356.8(a).

[10] *See Notice of Antidumping Duty Orders: Carbon and Certain Alloy Steel Wire Rod from Brazil, Indonesia, Mexico, Moldova, Trinidad and Tobago, and Ukraine,* 67 FR 65945 (October 29, 2002).

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submission for OMB Review; Comment Request; "Public Key Infrastructure (PKI) Certificate Action Form"

The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposals for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: United States Patent and Trademark Office, Commerce.

Title: Public Key Infrastructure (PKI) Certificate Action Form.

OMB Control Number: 0651–0045.

Form Number(s):

- PTO–2042

Type of Request: Regular.

Number of Respondents: 3,825 responses per year.

Average Hours per Response: The USPTO estimates that it will take the public approximately 30 minutes (0.50 hours) to read the instructions and subscriber agreement, gather the necessary information, prepare the Certificate Action Form, and submit the completed request.

Needs and Uses:

This information collection covers the Certificate Action Form (PTO–2042), which is used by the public to request a new digital certificate, revoke a current certificate, or recover a lost or corrupted certificate. Customers may also change the name listed on the certificate or associate the certificate with one or more Customer Numbers. A Customer Number allows an applicant to associate all correspondence and USPTO actions regarding multiple patent applications to a single address and name. The Certificate Action Form must include a notarized signature in order to verify the identity of the application. The Certificate Action Form has an accompanying subscriber agreement to ensure that customers understand their obligations regarding the use of the digital certificates and cryptographic software. When generating a new certificate, customers also register to receive a set of seven codes that will enable customers to recover a lost certificate online without having to contact USPTO support staff.

Frequency: On occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Nicholas A. Fraser, email: *Nicholas_A._Fraser@omb.eop.gov.* Once submitted, this request will be publicly available in electronic format through *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Further information can be obtained by:

- *Email: InformationCollection@uspto.gov.* Include ''0651–0045 copy request'' in the subject line of the message.
- *Mail:* Marcie Lovett, Records and Information Governance Division Director, Office of the Chief Technology Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before May 17, 2018 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov* or by fax to 202–395–5197, marked to the attention of Nicholas A. Fraser.

Marcie Lovett,

Records and Information Governance Division Director, Office of the Chief Technology Officer, United States Patent and Trademark Office.

[FR Doc. 2018–08020 Filed 4–16–18; 8:45 am]

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

Submission for OMB Review; Comment Request; ''Public Search Facility User ID and Badging''

The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: United States Patent and Trademark Office, Commerce.

Title: Public Search Facility User ID and Badging.

OMB Control Number: 0651–0041.

Forms:

- PTO–2030
- PTO–2224

Number of Respondents: 6,250 responses per year.

Average Hours per Response: The USPTO estimates that it will take the public between approximately 5 minutes (0.08 hours) and 10 minutes (0.17 hours) to complete the information in this collection, depending on the application. This includes the time to gather the necessary information, prepare the appropriate form, and submit the completed request to the USPTO.

Burden Hours: 500 hours.

Cost Burden: $1,501.96.

Needs and Uses:

This collection covers information that individuals submit in applications to establish a USPTO online access account. This application allows users to obtain, renew, or replace online access account cards which provide access to the electronic search system at the Public Search Facility. The public may apply for an online access account only at the Public Search Facility reference desk by providing the completed application (including contact information) and proper identification. The access account cards include a bar-coded user number and an expiration date. Users may renew their account card in person by validating and updating the required information and may obtain a replacement for a lost account card by providing proper identification. Users who wish to register for the voluntary training courses may do so by completing the appropriate form.

This collection also covers information in applications to establish, renew, or replace security identification badges issued under the authority provided in 41 CFR part 102–81 to members of the public who wish to access the Public Search Facility. Users may apply for a security badge in person at the USPTO Security Office by providing the completed application (including applicant and contact information) and presenting a valid form of identification with photograph. The security badges include a color photograph of the user and must be worn always while at the USPTO facilities.

Frequency: On occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Nicholas A. Fraser, email: *Nicholas_A._Fraser@omb.eop.gov.* Once submitted, the request will be publicly available in electronic format through *reginfor.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Further information can be obtained by:

- *Email: InformationCollection@uspto.gov.* Include ''0651–0041 copy request'' in the subject line of the message.
- *Mail:* Marcie Lovett, Records and Information Governance Division Director, Office of the Chief Information Technology Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before May 17, 2018 to Nicholas A. Fraser. OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov.or* by fax to 202–395–5167, marked to the attention of Nicholas A. Fraser.

Marcie Lovett,

Records and Information Governance Division Director, Office of the Chief Technology Officer, United States Patent and Trademark Office.

[FR Doc. 2018–08019 Filed 4–16–18; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Trademark Petitions

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on a proposed extension of an existing information collection: 0651–0061 (Trademark Petitions).

DATES: Written comments must be submitted on or before June 18, 2018.

ADDRESSES: You may submit comments by any of the following methods:

- *Email: InformationCollection@uspto.gov.* Include ''0651–0061 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Marcie Lovett, Records and Information Governance Division Director, Office of the Chief Technology Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Catherine Cain, Attorney Advisor, Office of the Commissioner for Trademarks, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–8946; or by email to *Catherine.Cain@uspto.gov* with ''0651–0061 comment'' in the subject line. Additional information about this collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The United States Patent and Trademark Office (USPTO) administers the Trademark Act, 15 U.S.C. 1051 *et seq.,* which provides for the registration of trademarks, service marks, collective trademarks and collective service marks, collective membership marks, and certification marks. Individuals and businesses that use or intend to use such marks in commerce may file an application to register their marks with the USPTO.

Individuals and businesses may also submit various communications to the USPTO, including letters of protest, requests to make special, responses to petition inquiry letters, petitions to make special, requests to restore a filing date, and requests for reinstatement. The USPTO uses the information described in this collection to process letters of protests, requests to make special, responses to petition inquiry letters, petitions to make special, requests to restore filing date, and requests for reinstatement. The information is used by the public for a variety of private business purposes related to establishing and enforcing trademark rights. Information relating to the registration of a trademark is made available to the public by the USPTO. However, the release of information in a letter of protest is controlled and may be available only upon request.

A letter of protest is an informal procedure whereby third parties who object to the registration of a mark in a pending application may bring to the attention of the USPTO evidence bearing on the registrability of the mark. A letter of protest must identify the application being protested and the proposed grounds for refusing registration and include relevant evidence to support the protest.

A request to make special may be submitted where an applicant requests that initial examination of an application be advanced out of its regular order because the mark in the application was the subject of an inadvertently cancelled or expired previous registration.

A response to a petition inquiry letter is submitted by a petitioner who is responding to a notice of deficiency that the USPTO issued after receiving an incomplete petition to the Director. A petition may be considered incomplete if, for example, it does not include the fee required by 37 CFR 2.6 or if it includes an unverified assertion that is not supported by evidence.

The USPTO generally examines applications in the order in which they are received. A petition to make special is a request by the applicant to advance the initial examination of an application out of its regular order.

A request to restore a filing date is submitted by an applicant who previously filed an application that was denied a filing date. The request must include evidence showing that the applicant is entitled to the earlier filing date.

If an applicant has proof that an application was inadvertently abandoned due to a USPTO error, an applicant may file a request to reinstate the application instead of a formal petition to revive. To support such a request, the applicant must include clear evidence of the USPTO error.

II. Method of Collection

Electronically, if applicants submit the information using the forms available through the Trademark Electronic Application System (TEAS). By mail or hand delivery, if applicants choose to submit the information in paper form.

III. Data

OMB Number: 0651–0061.

IC Instruments and Forms: N/A.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households; business or other for-profit organizations; not-for-profit organizations.

Estimated Number of Respondents: 4,768 responses per year.

Estimated Time per Response: The USPTO estimates that it will take approximately between 35 minutes (0.58 hours) to 75 minutes (1.25 hours) to complete items in this collection. This includes the time to gather the necessary information, create the documents, and submit the completed request to the USPTO.

Estimated Total Annual Respondent Burden Hours: 4,333.63 hours per year.

Estimated Total Annual Respondent (Hourly) Cost Burden: $1,898,129.94. The USPTO expects that an attorney will complete the instruments associated with this information collection. The professional hourly rate for attorneys is $438, which is the median professional rate for intellectual property attorneys in private firms as shown in the 2017 *Report of the Economic Survey* published by the American Intellectual Property Law Association (AIPLA). Using this hourly rate, the USPTO estimates that the total respondent cost burden for this collection is $1,898,129.94 per year.

IC No.	Item	Time for response (hours) (a)	Responses (b)	Burden hours (c) (a) × (d)	Rate (d)	Total cost (e) (c) × (d)
1	Letter of Protest (TEAS Global)	1 (60 minutes)	3,475	3,475.00	$438.00	$1,522,050.00
1	Letter of Protest (Paper)	1.25 (75 minutes)	10	12.50	438.00	5,475.00
2	Request to Make Special (TEAS Global).	0.58 (35 minutes)	150	87.00	438.00	38,106.00
2	Request to Make Special (Paper)	0.75 (45 minutes)	1	0.75	438.00	328.50
3	Response to Petition to Director Inquiry Letter (TEAS Global).	0.75 (45 minutes)	274	205.50	438.00	90,009.00
3	Response to Petition to Director Inquiry Letter (Paper).	1 (60 minutes)	1	1.00	438.00	438.00
4	Petition to Make Special (TEAS Global).	0.58 (35 minutes)	531	307.98	438.00	134,895.25
4	Petition to Make Special (Paper)	0.75 (45 minutes)	2	1.5	438.00	657.00
5	Request to Restore Filing Date (TEAS Global).	0.58 (35 minutes)	5	2.90	438.00	1,270.20
5	Request to Restore Filing Date (Paper).	0.75 (45 minutes)	1	0.75	438.00	328.50
6	Request for Reinstatement (TEAS Global).	0.75 (45 minutes)	317	237.75	438.00	104,134.50
6	Request for Reinstatement (Paper)	1 (60 minutes)	1	1.00	438.00	438.00
	Total		4,768	4,333.63		1,898,129.94

Estimated Total Annual (Non-hour) Respondent Cost Burden: $53,307.84 per year. This collection has no capital start-up, maintenance, or operating fees. This collection does have postage cost and filing fees.

Filing Fees

There are fees associated with this collection, specifically for the Petition to Make Special, which has a fee amount of $100 per respondent. The total estimated filing-fee cost for this collection is $53,300.00

IC No.	Item	Responses	Filing fee	Total cost
4	Petition to Make Special (TEAS Global)	531	$100.00	$53,100.00
4	Petition to Make Special (Paper)	2	100.00	200.00
	Totals	533		53,300.00

Postage Cost

Applicants incur postage costs when submitting non-electronic information to the USPTO by mail through the United States Postal Service (USPS). The USPTO estimates that the vast majority—approximately 98%—of the paper forms are submitted to the USPTO via first-class mail, while the rest are submitted by hand delivery. The USPTO estimates that 16 forms will be mailed. The average first-class USPS postage cost for a mailed submission is $0.50. Therefore, the USPTO estimates that the postage costs for the mailed submissions in this collection will total $8.

Therefore, the USPTO estimates that the total annual (non-hour) cost burden for this collection, in the form of filing fees ($53,300) and postage costs ($8), is $53,308 per year.

IV. Request for Comments

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection. They also will become a matter of public record.

Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) The accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on respondents, *e.g.,* the use of automated collection techniques or other forms of information technology.

Marcie Lovett,

Records and Information Governance Division Director, OCTO, United States Patent and Trademark Office.

[FR Doc. 2018–08021 Filed 4–16–18; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Third-Party Submissions and Protests

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on a proposed extension of an existing information collection: 0651–0062 (Third-Party Submissions and Protests).

DATES: Written comments must be submitted on or before June 18, 2018.

ADDRESSES: You may submit comments by any of the following methods:

- *Email: InformationCollection@uspto.gov.* Include ''0651–0062 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Marcie Lovett, Records and Information Governance Division Director, Office of the Chief Technology Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–7728; or by email to *Raul.Tamayo@upsto.gov* with ''0651–0062 comment'' in the subject line. Additional information about this collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The United States Patent and Trademark Office (USPTO) is required by 35 U.S.C. 131 *et seq.* to examine an application for patent and, when appropriate, issue a patent. The provisions of 35 U.S.C. 122(c), 122(e), 131, and 151, as well as 37 CFR 1.290 and 1.291, limit the ability of a third party to have information entered and considered in, or to protest, a patent application pending before the Office.

37 CFR 1.290 provides a mechanism for third parties to submit to the USPTO, for consideration and inclusion in the record of a patent application, any patents, published patent applications, or other printed publications of potential relevance to the examination of the application.

A third-party submission under 37 CFR 1.290 may be made in any non-provisional utility, design, and plant application, as well as in any continuing application. A third-party submission under 37 CFR 1.290 must include a concise description of the asserted relevance of each document submitted, and must be submitted within a certain statutorily specified time period.

37 CFR 1.291 permits a member of the public to file a protest against a pending application. Protests pursuant to 37 CFR 1.291 are supported by a separated statutory provision from third-party submissions under 37 CFR 1.290 (35 U.S.C. 122(c) v. 35 U.S.C. 122(e)). As a result, there are several differences between protests and third-party submissions.

For example, 37 CFR 1.291 permits the submission of information in a protest that is not permitted in a third-party submission under 37 CFR 1.290. Specifically, 37 CFR 1.291 provides for the submission of information, including any facts or information adverse to patentability. Further, 37 CFR 1.291 requires a protest to include a concise explanation of the relevance of each item of information submitted. Unlike the concise description of relevance required for a third-party submission under 37 CFR 1.290, which is limited to a description of a document's relevance, the concise explanation for a protest under 37 CFR 1.291 allows for arguments against patentability. Additionally, the specified time period for submitting a protest differs from the time period for submitting third-party submissions, and is impacted by whether the protest is accompanied by the written consent of the applicant.

Comparison	Third party submission	Protest
Statute/Rule	35 U.S.C. 122(e), 37 CFR 1.290	35 U.S.C. 122(c), 37 CFR 1.291.
Content	Printed publications	Printing publications and any facts or information adverse to patentability.
Remarks	Concise description of relevance (limited to a concise description of each document's relevance).	Concise explanation of the relevance (allows for arguments against patentability).
Timing	Prior to Allowance and prior to later of: 6 months after Pre-Grant Publication or first rejection of any claim.	Prior to Allowance and prior to Pre-Grant Publication OR Prior to Allowance and after and after Pre-Grant Publication with application consent.

This information collection is necessary so that the public may contribute to the quality of issued patents. The USPTO will use this information, as appropriate, to assist in evaluating the patent application as it moves through the patent examination process.

II. Method of Collection

OMB Number: 0651–0062.

IC Instruments: PTO/SB/429.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households; businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 1,450 responses per year.

Estimated Time per Response: The USPTO estimates that it will take the pubic approximately 10 hours to gather the necessary information, prepare the appropriate form or document, and submit the information to the USPTO.

Estimated Total Annual Hour Burden: 14,500 hours.

Estimated Annual Respondent (Hourly) Cost Burden: $6,351,000.00. The USPTO expects that intellectual property attorneys in private firms will complete the instruments associated with this information collection. The professional hourly rate is $438. The rate is established by estimates in the 2017 Report on the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association. Using this hourly rate, the USPTO estimates that the total respondent cost burden for this collection is $6,351,000 per year.

TABLE 1—BURDEN HOUR AND COST

IC No.	Item	Response time (hours) (a)	Responses (b)	Annual burden hours (c) (a) × (b)	Rate (d)	Total cost (e) (c) × (d)
1	Third-Party Submissions in Non-issued Applications (electronic).	10	1,400	14,000	$438.00	$6,132,000.00
2	Third-Party Submissions in Non-issued Applications (paper).	10	40	400	438.00	175,200.00
3	Protests by the Public Against Pending Applications Under 37 CFR 1.291 (paper).	10	10	100	438.00	43,800.00
Total			1,450	14,500		6,351,000.00

Estimated Total Annual (Non-hour) Respondent Cost Burden: $74,160 per year. There are no capital start-up, recordkeeping or maintenance costs associated with this information collection. There are, however, annual (non-hour) costs associated with this information collection in the forms of filing fees and postage costs. In particular, 37 CFR 1.290 requires payment of the fee set forth in 37 CFR 1.17(o) ($180 undiscounted; $90 for a small or micro entity) for every ten documents, or fraction thereof, listed in each third-party submission.

The USPTO provides an exemption from the 1.17(o) fee requirement where a third-party submission listing three or fewer total documents is the first third-party submission submitted in an application by the third party, or a party in privity with the third party. The effect of this is that the first three documents submitted by a third party are exempt from the fee requirement. However, the submission of four or more documents by a third party triggers the collection of the fee.

There is no fee for filing protests under 37 CFR 1.291 unless the filed protest is the second or subsequent protest by the same real party in interest, in which case the 37 CFR 1.17(i) fee of $130 must be included. The USPTO estimates that only 1 out of every 10 protests filed per year will require this fee.

When electronically submitting the information in this collection to the USPTO, the applicant is encouraged to retain a copy of the file submitted to the USPTO as evidence of the application. Inclusion of an USPS acknowledgement receipt with mailed items provides evidence of the date the file was received by the USPTO. The USPTO does not, however, require this recordkeeping, and thus does not consider this action to be a recordkeeping cost imposed on the applicant.

TABLE 2—FILING FEES

IC No.	Item	Estimated annual responses (a)	Filing fee ($) (b)	Total Non-hour cost burden ($) (a) × (b) = (c)
1–2	Third-Party Submissions in Non-issued Applications	410	$180.00	$73,800.00
1–2	Third-Party Submissions in Non-issued Applications (small and micro entities)	170	90.00	15,300.00
3	Protests by the Public Against Pending Applications Under 37 CFR 1.291	1	130.00	130.00
Total		581		73,930.00

This collection also has non-hourly annual cost burden in the form of postage costs. Customers may incur postage costs when submitting the instruments contained within this collection to the USPTO by mail through the United States Postal Service. The USPTO estimates that the average first class postage cost for a one-pound submission mailed in a flat-rate envelope to be $6.70. The USPTO estimates that the vast majority—roughly 98 percent—of all paper submissions will be delivered by mail, with the remainder being delivered by hand delivery, for an estimated that approximately 40 submissions will require postage. Therefore, the estimated postage cost for this collection will be $268.

The total non-hour respondent cost burden for this collection in the form of filing fees ($73,930) and postage costs ($268) is approximately $74,198.

IV. Request for Comments

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection. They will also become a matter of public record.

Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) The accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on respondents, *e.g.,* the use of automated

collection techniques or other forms or information technology.

Marcie Lovett,

Records and Information Governance Division Director, OCTO, United States Patent and Trademark Office.

[FR Doc. 2018–08022 Filed 4–16–18; 8:45 am]

BILLING CODE 3510–16–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2018–0014]

Request for Information Regarding the Bureau's Consumer Complaint and Consumer Inquiry Handling Processes

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for information.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau) is seeking comments and information from interested parties to assist the Bureau in assessing its handling of consumer complaints and consumer inquiries and, consistent with law, considering whether changes to its processes would be appropriate.

DATES: Comments must be received by July 16, 2018.

ADDRESSES: You may submit responsive information and other comments, identified by Docket No. CFPB–2018–0014, by any of the following methods:

- *Electronic:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: FederalRegisterComments@cfpb.gov.* Include Docket No. CFPB–2018–0014 in the subject line of the message.
- *Mail:* Comment Intake, Consumer Financial Protection Bureau, 1700 G Street NW, Washington, DC 20552.
- *Hand Delivery/Courier:* Comment Intake, Consumer Financial Protection Bureau, 1700 G Street NW, Washington, DC 20552.

Instructions: The Bureau encourages the early submission of comments. All submissions must include the document title and docket number. Please note the number of the topic on which you are commenting at the top of each response (you do not need to address all topics). Because paper mail in the Washington, DC area and at the Bureau is subject to delay, commenters are encouraged to submit comments electronically. In general, all comments received will be posted without change to *http://www.regulations.gov.* In addition, comments will be available for public inspection and copying at 1700 G Street NW, Washington, DC 20552, on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. You can make an appointment to inspect the documents by telephoning 202–435–7275.

All submissions in response to this request for information, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Proprietary information or sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Darian Dorsey, Deputy Assistant Director, Office of Consumer Response, at 202–435–7268. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION: An important aspect of the Bureau's mission is hearing directly from the American public about their experiences in the consumer financial marketplace. Pursuant to 12 U.S.C. 5511(c)(2), ''collecting, investigating, and responding to consumer complaints'' is one of the six statutory ''primary functions'' of the Bureau. In addition, ensuring that ''consumers are provided with timely and understandable information to make responsible decisions about financial transactions'' is one of its six enumerated objectives.[1]

In furtherance of these statutory mandates, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) requires the Bureau to establish a unit to ''facilitate the centralized collection of, monitoring of, and response to consumer complaints regarding consumer financial products or services'' [2] and directs the Bureau to establish reasonable procedures to provide timely responses to consumer complaints and consumer inquiries.[3] The Bureau defines *consumer complaints* as ''submissions that express dissatisfaction with, or communicate suspicion of wrongful conduct by, an identifiable entity related to a consumer's personal experience with a financial product or service.'' [4] To date, the Bureau has not published its definition of *consumer inquiries;* however, as an operational matter for the purposes of establishing reasonable procedures for providing timely responses to consumer inquiries and for the purposes of this request for information, the Bureau defines *consumer inquiries* as consumer requests for information—typically proffered by telephone—to its Office of Consumer Response about consumer financial products or services, the status of a complaint, an action taken by the Bureau, and often combinations thereof.[5]

Since it began accepting consumer complaints and consumer inquiries in July 2011, the Bureau has established reasonable procedures to provide consumers with timely responses to their complaints and inquiries, in writing where appropriate.[6] To date, the Bureau has received more than 1.5 million consumer complaints. The consumer complaint process seeks to provide consumers with timely responses to their complaints, while the consumer inquiry process aims to provide timely answers to consumers who submit inquiries. Both processes support the Bureau's statutory objective to provide consumers with timely and understandable information about consumer financial products and services to make responsible decisions. To that end, the Bureau has established reasonable procedures for responding to both consumer complaints and consumer inquiries.

Though the Bureau is required to establish reasonable procedures to provide timely responses to consumer complaints and consumer inquiries, certain aspects of the complaint and inquiry handling processes were developed in furtherance of those statutory requirements but are not directly mandated by statute. Mindful of the Bureau's statutory objective to provide consumers with timely and understandable information about consumer financial products and services so they can make responsible decisions, as well as its statutory obligations to (1) establish reasonable procedures to provide consumers with timely responses and (2) centralize the collection of consumer complaints about consumer financial products or

[1] 12 U.S.C. 5511(b)(1).

[2] The Bureau's Office of Consumer Response (''Consumer Response'') serves these and other functions. 12 U.S.C. 5493(b)(3)(A).

[3] 12 U.S.C. 5534(a).

[4] Consumer Financial Protection Bureau, *Consumer Response Annual Report* (Mar. 2012), *available at http://files.consumerfinance.gov/f/201204_cfpb_ConsumerResponseAnnualReport.pdf.*

[5] 12 U.S.C. 5511(b)(1) authorizes the Bureau to ensure that, with respect to consumer financial products and services, ''consumers are provided with timely and understandable information to make responsible decisions about financial transactions''; some of this work occurs in the consumer complaint and inquiry processes performed within the Office of Consumer Response.

[6] 12 U.S.C. 5534(a).

services, the Bureau has used feedback from a variety of stakeholders to establish and refine its processes over time to improve stakeholders' experience, handle large volumes of complaints and inquiries,[7] and increase overall efficiency.

Consumer Complaint Process. To ''facilitate the centralized collection of, monitoring of, and response to consumer complaints regarding consumer financial products or services,'' the Bureau accepts complaints through its website; by referral from the White House, congressional offices, Federal agencies, and State agencies; and by telephone, mail, email, and fax. When consumers [8] choose to submit complaints, the Bureau's complaint form prompts them to select the consumer financial product or service with which they have a problem as well as the type of problem they are having with that product or service. This provides information that can be used to group complaints to understand the financial products and services about which consumers complain to the Bureau. The complaint form also requires consumers to affirm that the information provided in their complaint is true to the best of their knowledge and belief. The Bureau routes complaints about consumer financial products and services directly to financial companies and works with them to get consumers a timely response from the company, generally within 15 days. Where appropriate, complaints are routed to other Federal agencies.[9] The company reviews the information, communicates with the consumer as needed, and determines what action to take in response. The company then responds to the consumer and the Bureau in writing via the secure company portal, and the Bureau invites the consumer to review the company's response and provide feedback about the response received from the company. Consumers can log onto the secure consumer portal available on the Bureau's website or call the Bureau to receive status updates, provide additional information, and review responses provided by the company. In 2017, the Bureau handled more than 320,000 consumer complaints.[10]

Consumer Inquiry Process. The Bureau's single, toll-free telephone number [11] gives consumers the opportunity to ask questions about financial products or services, submit a complaint, and check the status of a complaint. Consumers can also inquire about the Bureau and a subset of its recent actions. When consumers call with an inquiry about consumer financial products or services, a Bureau representative collects basic information about the consumer, listens to the consumer describe their situation and question, and provides clear, unbiased educational information about financial products and services. Representatives do not provide legal advice to consumers, nor do they encourage consumers to take any particular action. Instead, when appropriate, representatives direct consumers to Bureau educational materials and tools, and other relevant government resources. The Bureau's U.S.-based contact center provides services to consumers in more than 180 languages and to consumers who are deaf, have hearing loss, or have speech disabilities. In 2017, the Bureau received more than 200,000 consumer inquiries.

Overview of This Request for Information

The Bureau is using this request for information (RFI) to seek public input regarding potential changes that can be implemented to the Bureau's consumer complaint and inquiry handling processes, consistent with law, to consider whether any changes to existing practices would be appropriate given the Bureau's statutory objective to provide consumers with timely and understandable information about consumer financial products and services to make responsible decisions as well as its statutory obligations to (1) establish reasonable procedures to provide timely responses to consumers and (2) centralize the collection of consumer complaints regarding consumer financial products or services. The Bureau encourages comments from all interested members of the public, including financial industry participants, government agencies, academic and research organizations, consumer advocacy and financial education groups, trade associations, and consumers.

The Bureau previously issued an RFI seeking public input regarding potential changes that can be implemented to the Bureau's public reporting practices of consumer complaint information, consistent with law, to consider whether any changes to the practices would be appropriate.[12] The Bureau will consider for the purposes of this RFI, and to the extent relevant, all comments previously received in connection with that request. Respondents, therefore, should not feel any obligation to include in their responses to this RFI suggestions and comments already submitted in response to the call for evidence on public reporting practices of consumer complaint information.

Suggested Topics for Commenters

To allow the Bureau to evaluate suggestions more effectively, the Bureau requests that, where possible, comments include:

- Specific discussion of the positive and negative aspects of the Bureau's complaint and inquiry processes;
- Specific suggestions regarding any potential updates or modifications to the Bureau's complaint and inquiry processes, consistent with the law and given one of the Bureau's statutory obligations is to establish reasonable procedures to provide consumers with timely responses to complaints and inquiries, including, in as much detail as possible, the nature of the modification, and supporting data or other information on impacts and costs;
- Specific best practices for complaint and inquiry processes given the Bureau's statutory objectives and functions, including ensuring consumers are provided with timely and understandable information to make responsible decisions about financial transactions [13] and centralizing the collection of consumer complaints about consumer financial products or services.

The following represents a preliminary attempt by the Bureau to identify elements of the Bureau's complaint and inquiry processes on which commenters may want to comment. This non-exhaustive list is meant to assist in the formulation of comments and is not intended to restrict the issues that may be addressed. In addressing these issues and questions, the Bureau requests that commenters identify with specificity the complaint or inquiry processes feature at issue, providing legal citations where appropriate and available.

[7] In 2017, the Bureau received more than 500,000 consumer complaints and consumer inquiries.

[8] The term 'consumer' means an individual or an agent, trustee, or representative acting on behalf of an individual.'' 12 U.S.C. 5481(4)

[9] The Bureau refers or sends complaints to another regulator when, for example, a particular complaint does not involve a product or service currently handled by the Bureau.

[10] Consumer Financial Protection Bureau, *Consumer Response Annual Report* (Apr. 2018), *available at https://www.consumerfinance.gov/documents/6406/cfpb_consumer-response-annual-report_2017.pdf.*

[11] 12 U.S.C. 5493(b)(3)(A).

[12] Request for Information Regarding Bureau Public Reporting Practices of Consumer Complaint Information, 83 FR 9499 (March 6, 2018).

[13] 12 U.S.C. 5511(b)(1).

The Bureau is seeking feedback on all aspects of its consumer complaint and inquiry handling processes, including:

1. Specific statutorily-permissible suggestions regarding how the Bureau currently allows consumers to submit complaints and inquiries, including:

a. Should the Bureau require consumers to classify their submission affirmatively as a consumer complaint or inquiry prior to submission?

b. How should the Bureau explain the difference between a consumer complaint and a consumer inquiry to consumers at the point of submission?

c. Should the Bureau develop a process for companies to reclassify consumers' submissions? If so, what criteria should the Bureau establish to help companies differentiate consumer complaints from consumer inquiries?

2. Specific statutorily-permissible suggestions regarding the Bureau's consumer complaint processes, including:

a. The Bureau currently receives complaints via six channels: Website, referral from Federal and State entities/agencies, telephone, mail, fax, and email. Should the Bureau add or discontinue any channels for accepting complaints?

b. Consistent with the Dodd-Frank Act's definition of ''consumer,'' the Bureau currently allows consumers to authorize someone else (*e.g.,* lawyer, advocate, power of attorney) to submit complaints on their behalf. Should the Bureau expand, limit, or maintain the ability of authorized third parties to submit complaints?

3. Specific statutorily-permissible suggestions regarding the Bureau's consumer inquiry processes, including:

a. The Bureau currently accepts consumer inquiries via telephone and mail. Should the Bureau add or discontinue any channels for accepting inquiries?

b. Should the Bureau develop web chat systems to support consumers' submission of inquiries?

c. Should the Bureau develop a process for companies to provide timely responses to consumer inquiries sent to them by the Bureau? If so, how should the Bureau balance its objective of providing timely and understandable information to consumers [14] with its objective of reducing unwarranted regulatory burden on companies? [15]

d. Should the Bureau publish data about consumer inquiries? If so, what types of data or analyses about consumer inquiries should be shared with the public?

[14] 12 U.S.C. 5511(b)(1).

[15] 12 U.S.C. 5511(b)(3).

Authority: 12 U.S.C. 5511(c).

Dated: April 10, 2018.

Mick Mulvaney,

Acting Director, Bureau of Consumer Financial Protection.

[FR Doc. 2018–07943 Filed 4–16–18; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2018–OS–0019]

Joint Rules of Appellate Procedure for Courts of Criminal Appeals; Proposed Changes

AGENCY: Joint Rules of Appellate Procedure for Courts of Criminal Appeals (JRAP) Committee, Department of Defense.

ACTION: Notice of availability of proposed changes to the Joint Rules of Appellate Procedure for Courts of Criminal Appeals.

SUMMARY: This notice announces proposed changes to the Joint Rules of Appellate Procedure for Courts of Criminal Appeals (JRAP), which prescribe uniform procedures for the service Courts of Criminal Appeals. Although these rules of practice and procedure fall within the Administrative Procedure Act's exemptions for notice and comment, the Department, as a matter of policy, has decided to make these changes available for public review and comment before they are implemented. The proposed changes implement the Military Justice Act of 2016 of the National Defense Authorization Act of 2017 and the 2018 Amendments to the Manual for Courts-Martial, United States. The approval authorities for these changes are the Judge Advocates General of the Army, Navy, Air Force, and Coast Guard.

DATES: Comments on the proposed changes must be received no later than May 17, 2018.

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

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, 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: Lieutenant Commander Rachel Trest, JAGC, USN, United States Navy-Marine Corps Court of Criminal Appeals, (202) 685–4621, *rachel.e.trest@navy.mil.*

SUPPLEMENTARY INFORMATION: As the proposed revisions to the JRAP are substantial, the full text of the proposed new JRAP is available electronically at *www.regulations.gov,* searchable by Docket ID: DoD–2018–OS–0019. The current text of the JRAP is available for comparison electronically at *www.regulations.gov,* searchable by Docket ID: DoD–2018–OS–0019.

The JRAP Committee invites members of the public to comment on the proposed new rules; such comments should address specific recommended changes and provide supporting rationale.

This notice is intended only to improve the internal management of the Federal Government. It is not intended to create any right or benefit, substantive or procedural, enforceable at law by any party against the United States, its agencies, its officers, or any person.

Dated: April 10, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–07965 Filed 4–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0007]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Teacher Education Assistance for College and Higher Education Grant Program (TEACH Grant Program) Agreement To Serve

AGENCY: Federal Student Aid (FSA), 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 May 17, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2018–ICCD–0007. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 216–34, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Jon Utz, 202–377–4040.

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: Teacher Education Assistance for College and Higher Education Grant Program (TEACH Grant Program) Agreement to Serve.

OMB Control Number: 1845–0083.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 50,793.

Total Estimated Number of Annual Burden Hours: 25,397.

Abstract: As a condition for receiving a TEACH Grant, a student must sign an Agreement to Serve. A new Agreement to Serve must be signed for each award year during which a student wishes to receive a TEACH Grant. By signing the Agreement to Serve, a TEACH Grant recipient agrees to meet the teaching service obligation and other terms and conditions of the TEACH Grant Program that are described in the Agreement to Service. In accordance with these terms and conditions, if a TEACH Grant recipient does not fulfill the required teaching service obligation or otherwise fails to meet the requirements of the TEACH Grant Program, any TEACH Grant funds the individual received will be converted to a Direct Unsubsidized Loan that the grant recipient must repay in full, with interest. The Agreement to Serve also explains the repayment terms and conditions that will apply if a TEACH Grant is converted to a Direct Unsubsidized Loan.

Dated: April 11, 2018.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–07940 Filed 4–16–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of Renewal.

SUMMARY: Pursuant to the Federal Advisory Committee Act, and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the Environmental Management Site-Specific Advisory Board (EM SSAB or Board) will be renewed for a two-year period beginning on April 11, 2018.

The Board provides the Assistant Secretary for Environmental Management (EM) with advice and recommendations concerning issues affecting the EM program at various sites. These site-specific issues include clean-up standards and environmental restoration; waste management and disposition; stabilization and disposition of non-stockpile nuclear materials; excess facilities; future land use and long-term stewardship; risk assessment and management; and clean-up science and technology activities.

Additionally, the renewal of the Board has been determined to be essential to conduct DOE's business and to be in the public interest in connection with the performance of duties imposed on the DOE by law and agreement. The Board will operate in accordance with the provisions of the Federal Advisory Committee Act, and rules and regulations issued in implementation of that Act.

FOR FURTHER INFORMATION CONTACT: Mr. David Borak, Designated Federal Officer, at (202) 586–9928 or *david.borak@em.doe.gov.*

Issued in Washington, DC, on April 11, 2018.

Wayne D. Smith,

Committee Management Officer.

[FR Doc. 2018–07995 Filed 4–16–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years, an information collection request with the Office of Management and Budget (OMB). Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments regarding this proposed information collection must be received on or before June 18, 2018. If you anticipate difficulty in submitting comments within that period, contact the person listed in the **FOR FURTHER**

INFORMATION CONTACT section as soon as possible.

ADDRESSES: Written comments may be sent to Alesia Gant, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585–1615, or by email at *alesia.gant@hq.doe.gov;* Ms. Gant may also be contacted at (202) 287–1476.

FOR FURTHER INFORMATION CONTACT: Alesia Gant at the address listed in **ADDRESSES**. Reporting requirements can be found at: *https://energy.gov/sites/prod/files/2016/01/f28/Policy%20Flash%202016-11%20-%20Model%20H-Clause%201-14-16.pdf.*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No. 1910–0600; (2) Information Collection Request Titled: Industrial Relations; (3) Type of Review: Renewal; (4) Purpose: This information is required for management oversight of the Department of Energy's Facilities Management Contractors and to ensure that the programmatic and administrative management requirements of the contract are managed efficiently and effectively; (5) Annual Estimated Number of Respondents: 42; (6) Annual Estimated Number of Total Responses: 316; (7) Annual Estimated Number of Burden Hours: 4,093; (8) Annual Estimated Reporting and Recordkeeping Cost Burden: $0.

Statutory Authority: 42 U.S.C. 7256; 48 CFR 970.0370–1.

Issued in Washington, DC, on March 14, 2018.

John R. Bashista,

Director, Office of Acquisition Management.

[FR Doc. 2018–07994 Filed 4–16–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board Chairs

AGENCY: Department of Energy (DOE).

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB) Chairs. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, May 3, 2018, 8:00 a.m.–5:00 p.m.

ADDRESSES: Holiday Inn Roswell, 3620 North Main Street, Roswell, New Mexico 88201.

FOR FURTHER INFORMATION CONTACT: David Borak, EM SSAB Designated Federal Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585; Phone: (202) 586–9928.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda Topics:

Thursday, May 3, 2018

- EM Program Update
- EM SSAB Chairs' Round Robin
- Budget and Planning Update
- Waste Disposition and Regulatory Reform Update
- Public Comment
- EM SSAB Chairs' Recommendation(s) Development and Discussion
- EM SSAB Designated Federal Officer's Update

Public Participation: The EM SSAB Chairs welcome the attendance of the public at their advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact David Borak at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed either before or after the meeting with the Designated Federal Officer, David Borak, at the address or telephone listed above. Individuals who wish to make oral statements pertaining to agenda items should also contact David Borak. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling David Borak at the address or phone number listed above. Minutes will also be available at the following website: *https://energy.gov/em/listings/chairs-meetings.*

Issued at Washington, DC on April 11, 2018.

Latanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2018–08001 Filed 4–16–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 18–35–LNG]

Sabine Pass Liquefaction, LLC; Application for Blanket Authorization To Export Previously Imported Liquefied Natural Gas on a Short-Term Basis

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt of an application (Application), filed on March 23, 2018, by Sabine Pass Liquefaction, LLC (SPL), requesting blanket authorization to export liquefied natural gas (LNG) previously imported into the United States from foreign sources in an amount up to the equivalent of 500 billion cubic feet (Bcf) of natural gas on a short-term or spot market basis for a two-year period commencing on June 7, 2018. SPL states that the existing blanket re-export authorization of its affiliate, Cheniere Marketing, LLC, set forth in DOE/FE Order No. 3825 (May 26, 2016) is scheduled to expire on June 6, 2018. SPL seeks authorization to export the LNG from the Sabine Pass LNG Terminal owned by Sabine Pass LNG, L.P. and located in Cameron Parish, Louisiana, to any country with the capacity to import LNG via ocean-going carrier and with which trade is not prohibited by U.S. law or policy. SPL states that it does not seek authorization to export any domestically produced natural gas or LNG. SPL is requesting this authorization on its own behalf and as agent for other parties who hold title to the LNG at the time of export. The Application was filed under section 3 of the Natural Gas Act (NGA). Additional details can be found in SPL's Application, posted on the DOE/FE website at: *https://www.energy.gov/sites/prod/files/2018/04/f50/18-35-LNG.pdf.* Protests, motions to intervene, notices of intervention, and written comments are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed using procedures detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, May 17, 2018.

ADDRESSES:

Electronic Filing by email: fergas@hq.doe.gov.

Regular Mail: U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of

Fossil Energy, P.O. Box 44375, Washington, DC 20026–4375.

Hand Delivery or Private Delivery Services (e.g., FedEx, UPS, etc.): U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Beverly Howard or Larine Moore, U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9387; (202) 586–9478.

Cassandra Bernstein or R.J. Colwell, U.S. Department of Energy Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, Room 6D–033, 1000 Independence Ave. SW, Washington, DC 20585, (202) 586–9793 or 586–8499.

SUPPLEMENTARY INFORMATION:

DOE/FE Evaluation

The Application will be reviewed pursuant to section 3 of the NGA, 15 U.S.C. 717b. In reviewing this Application, DOE will consider domestic need for the gas, as well as any other issues determined to be appropriate, including whether the arrangement is consistent with DOE's policy of promoting competition in the marketplace by allowing commercial parties to freely negotiate their own trade arrangements. Parties that may oppose this application should comment in their responses on these issues.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.,* requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable. Interested parties will be provided 30 days from the date of publication of this Notice in which to submit comments, protests, motions to intervene, or notices of intervention.

Any person wishing to become a party to the proceeding must file a motion to intervene or notice of intervention. The filing of comments or a protest with respect to the Application will not serve to make the commenter or protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by the regulations in 10 CFR part 590.

Filings may be submitted using one of the following methods: (1) Emailing the filing to *fergas@hq.doe.gov,* with FE Docket No. 18–35–LNG in the title line; (2) mailing an original and three paper copies of the filing to the Office of Regulation and International Engagement at the address listed in **ADDRESSES**; or (3) hand delivering an original and three paper copies of the filing to the Office of Regulation and International Engagement at the address listed in **ADDRESSES**. All filings must include a reference to FE Docket No. 18–35–LNG. **Please Note:** If submitting a filing via email, please include all related documents and attachments (*e.g.,* exhibits) in the original email correspondence. Please do not include any active hyperlinks or password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner. Any hardcopy filing submitted greater in length than 50 pages must also include, at the time of the filing, a digital copy on disk of the entire submission.

A decisional record on the Application will be developed through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Opinion and Order may be issued based on the official record, including the Application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

The Application is available for inspection and copying in the Office of Regulation and International Engagement docket room, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The Application and any filed protests, motions to intervene or notice of interventions, and comments will also be available electronically by going to the following DOE/FE Web address: *http://www.fe.doe.gov/programs/gasregulation/index.html.*

Issued in Washington, DC, on April 11, 2018.

Robert Smith,

Deputy Assistant Secretary for Oil and Natural Gas (Acting).

[FR Doc. 2018–07894 Filed 4–16–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commissioner Attendance at House Committee on Energy and Commerce Hearing

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission may attend the following hearing:

The House Committee on Energy and Commerce will be holding a general oversight hearing entitled ''Oversight of the Federal Energy Regulatory Commission and the FY2019 Budget.'' All five Commission members may testify at the hearing.

2123 Rayburn House Office Building, Washington, DC

April 17, 2018 at 10:00 a.m. eastern time

Further information regarding this hearing may be found at: *https://energycommerce.house.gov/hearings/.*

The discussions at the hearing, which are open to the public, may address issues relevant to Commission proceedings.

For further information, please contact Jehmal Hudson, 202–502–6142, or *jehmal.hudson@ferc.gov.*

Dated: April 10, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–07925 Filed 4–16–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD18–12–000; Docket No. EL17–45–000; Docket No. ER18–370–000]

Supplemental Notice of Technical Conference; Transmission Planning Within the California Independent System Operator Corporation; California Public Utilities Commission, Northern California Power Agency, City and County of San Francisco, State Water Contractors, Transmission Agency of Northern California v. Pacific Gas and Electric Company, Southern California Edison Company

As announced in the Notice of Technical Conference issued on March 23, 2018, the Federal Energy Regulatory Commission staff will hold a technical conference on May 1, 2018, at the Commission's headquarters at 888 First Street NE, Washington, DC 20426, between 9:00 a.m. and 4:00 p.m. (Eastern Time). The purpose of the technical conference is to explore the processes used by participating transmission owners (PTOs) in the California Independent System Operator Corporation (CAISO) to determine which transmission-related maintenance and compliance activities/facilities, including, but not limited to, transmission-related capital additions, are subject to the CAISO Transmission Planning Process (TPP).[1]

In Order No. 890, the Commission required all public utility transmission providers, including regional transmission organizations (RTOs) and independent system operators (ISOs), to revise their open access transmission tariffs (OATTs) to incorporate a transmission planning process that satisfied nine transmission planning principles to limit the opportunities for undue discrimination and anticompetitive conduct in transmission service.[2] In Order No. 890–A, the Commission noted that each RTO and ISO may fulfill its obligations under Order No. 890 by delegating certain planning activities to, or otherwise relying on, its transmission owning members, provided that the rights and responsibilities of all parties are clearly stated in the RTO's/ISO's OATT.[3] The Commission also explained that, in many cases, RTO/ISO transmission planning processes may focus principally on regional problems and solutions, while local planning issues may be addressed by individual transmission owners.[4] Noting that these local transmission planning issues may be critically important to transmission customers, the Commission stated that transmission owners must, to the extent that they perform transmission planning within an RTO or ISO, comply with Order No. 890 as well.[5]

In a series of orders issued between 2008 and 2010, the Commission accepted CAISO's TPP as consistent with the requirements of Order No. 890.[6] As is relevant here, in an order issued on May 21, 2009, the Commission found that ''the local planning activities conducted by the participating transmission owners [in CAISO] are reasonable and the process, as set forth in the [CAISO] tariff and business practice manual, is transparent.'' [7] However, more recently, a number of interested parties have raised concerns regarding the lack of opportunity for stakeholder review of transmission-related maintenance and compliance activities, including, but not limited to, certain transmission-related capital additions, which CAISO PTOs do not submit to CAISO's TPP.[8]

In an order issued March 23, 2018 in Docket No. ER18–370–000,[9] the Commission found that protesters in that proceeding raised important questions that relate to the processes by which all CAISO PTOs [10] determine which transmission-related maintenance and compliance activities, including, but not limited to, transmission-related capital additions, must be submitted to CAISO's TPP.[11] In that order, the Commission directed Commission staff to convene a technical conference to explore these issues.

Given the background provided herein, participants should be prepared to discuss the following:

1. Please define and describe what constitutes transmission-related maintenance and compliance activities/facilities. Please provide specific examples and an explanation regarding how it is determined that such an example falls into the category of transmission-related maintenance and compliance activities/facilities. How does each CAISO PTO identify the need for transmission-related maintenance and compliance activities/facilities and decide which activities/facilities to undertake?

2. How does each CASIO PTO determine if actions taken to maintain, repair, or replace facilities should be considered and reviewed through CAISO's TPP? Which transmission-related maintenance and compliance activities/facilities are submitted for consideration and review through CAISO's TPP and which activities or transmission facilities are considered and reviewed solely by PTOs? Please explain.

3. Are there criteria or parameters that each CAISO PTO uses to determine which transmission-related maintenance and compliance activities/facilities to submit to CAISO for consideration and review through CAISO's TPP? What factors are considered (*e.g.,* cost, voltage level, length, rating)? Please explain.

4. Do CAISO's tariff or BPMs provide guidance and clarity to CAISO PTOs regarding what transmission-related maintenance and compliance activities/facilities must be considered and reviewed through CAISO's TPP? If so, please list the relevant sections.

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[1] Commission staff is using ''transmission-related maintenance and compliance activities/facilities'' as a term intended to encompass the activities, facilities, and/or projects at issue in the proceedings included in this notice. The Parties in these proceedings do not use a common definition or phrase that is set out in any tariff or business practice manual (BPM). Staff's intent for the technical conference is to include a broad category of transmission-related activities and facilities. This includes any work on the transmission system, including, but not limited to, transmission-related maintenance, repair, replacement, or compliance activities and associated facilities, as well as transmission-related capital additions.

[2] Order No. 890, FERC Stats. & Regs. ¶ 31,241 at PP 426, 435; *see* Order No. 890–A, FERC Stats. & Regs. ¶ 31,261 at P 171. These transmission planning principles are: (1) Coordination; (2) openness; (3) transparency; (4) information exchange; (5) comparability; (6) dispute resolution; (7) regional participation; (8) economic planning studies; and (9) cost allocation for new projects.

[3] Order No. 890–A, FERC Stats. & Regs. ¶ 31,261 at P 175.

[4] Order No. 890, FERC Stats. & Regs. ¶ 31,241 at P 440.

[5] *Id.*

[6] *See Cal. Indep. Sys. Operator Corp.,* 123 FERC ¶ 61,283 (2008), *order denying reh'g and on compliance filing,* 127 FERC ¶ 61,172 (2009), *order on compliance filing,* 130 FERC ¶ 61,048 (2010).

[7] *Cal. Indep. Sys. Operator Corp.,* 127 FERC ¶ 61,172 at P 118.

[8] *See, e.g., Cal. Pub. Utils. Comm'n, et al.* v. *Pacific Gas & Elec. Co.,* Complaint, Docket No. EL17–45–000 (filed Feb. 2, 2017) (asserting that Pacific Gas & Electric Co. is in violation of Order No. 890 because it conducts more than 80 percent of its transmission planning on an internal basis without stakeholder review); Cal. Pub. Utils. Comm'n Dec. 22, 2017 Protest, Docket No. ER18–370–000 (protesting Southern California Edison Co.'s filing of an amendment to its Transmission Owner Tariff to create an annual Transmission Maintenance and Compliance Review process on the basis that the proposed process does not meet the requirements of Order No. 890).

[9] *S. Cal. Edison,* 162 FERC ¶ 61,264 (2018).

[10] Although the concerns protesters raised in Docket No. ER18–370–000 relate specifically to SoCal Edison, the Commission found that the questions raised were also applicable to the processes that other CAISO PTOs use to identify which transmission-related maintenance and compliance activities/facilities must be submitted to CAISO's TPP. *Id.* P 24.

[11] *Id.* P 23.

5. For transmission-related maintenance and compliance activities/facilities that may enhance the transmission system (such as additions that increase line ratings or extend the useful life of a transmission asset), how does each CAISO PTO determine whether this maintenance or compliance activity/facility should be considered and reviewed as part of CAISO's TPP? Where are the criteria or parameters related to this determination documented or otherwise made available?

6. When deciding whether to submit a transmission-related maintenance and compliance activity/facility for consideration and review through CAISO's TPP, does each CAISO PTO differentiate between transmission-related maintenance and compliance activities/facilities that require immediate action (*e.g.,* non-functioning transmission infrastructure) and those that do not require immediate action and may be addressed over a longer timeframe? Please explain how this differentiation is decided. Are there criteria or parameters used by the CAISO PTO to make this differentiation? If so, where are such criteria or parameters documented or otherwise made available?

7. Is there a process through which each CAISO PTO evaluates whether a transmission-related maintenance and compliance activity/facility that was not initially submitted to CAISO's TPP should be transitioned into the CAISO TPP for consideration and review? If so, please describe that process, including what criteria or parameters are considered in reaching the conclusion to transition to CAISO's TPP. Also, please explain where such criteria or parameters are documented or otherwise made available.

8. What information does each CAISO PTO submit to CAISO (during Phase I of the TPP) concerning the transmission-related maintenance and compliance activities/facilities planned outside of CAISO's TPP? Please explain what type of information is provided and what level of detail is included.

9. What is the process through which each CAISO PTO performs transmission planning activities outside of CAISO's TPP? Please describe that process in detail.

10. Are there processes for stakeholders to review and provide input on transmission-related maintenance and compliance activities/facilities, including transmission-related capital additions, not included in CAISO's TPP? If so, please describe these processes in detail, including whether there is an opportunity for stakeholders to review and provide input on cost and other factors. Please also describe the timeframe for providing this input.

11. How does each CAISO PTO decide whether to pursue reliability-related transmission-related maintenance and compliance activities/facilities that are not required by the North American Electric Reliability Corporation (NERC), Western Electricity Coordinating Council (WECC), or other regulatory entities? What criteria or parameters are used by each CAISO PTO to make this decision? Where are such criteria or parameters documented or otherwise made available?

12. Is there a difference between (a) the process through which each CAISO PTO pursues solutions to transmission-related maintenance and compliance activities/facilities that arise from NERC and WECC reliability standards or reliability standards established by other regulatory entities, and (b) the process through which each CAISO PTO pursues solutions to other transmission-related maintenance and compliance activities/facilities? If so, please explain (1) the difference between the two processes and (2) elaborate on the reasons for the differences.

13. Please explain how costs associated with transmission-related maintenance and compliance activities/facilities developed outside of the CAISO TPP are reflected in wholesale and retail transmission rates.

14. How does each CAISO PTO determine whether transmission-related maintenance, repair, or replacement activities/facilities should be capitalized or expensed as operations and maintenance costs? Please explain.

15. What recommendations do you have for each CAISO PTO to increase the transparency of the process for stakeholders and others with respect to the CAISO PTOs' planning for transmission-related maintenance and compliance activities/facilities? How would these recommendations affect the CAISO PTOs? Would such effects be manageable? If not, why not? If changes to increase transparency could be made, should they be the same for each CAISO PTO?

The technical conference will be led by Commission staff, and is open to the public. All interested persons may attend the conference, and registration is not required. However, in-person attendees are encouraged to register on-line by April 20, 2018 at *https://www.ferc.gov/whats-new/registration/05-01-18-form.asp.* This event will NOT be webcast. However, for those who cannot attend in person, we will provide a listen-only telephone line, if requested. Those wishing this service should register at the link provided and specify the telephone line option.

The conference will consist of questions posed by Commission staff and responses provided by CAISO, the CAISO PTOs, and complainants. There may also be an opportunity for follow-up questions and comments from attendees during those discussions. The specific agenda and procedures to be followed at the conference will be announced by staff at the opening of the conference.

The technical conference will be transcribed, and the transcript will be available immediately for a fee from Ace Reporting Company ((202) 347–3700).

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or (202) 502–8659 (TTY), or send a fax to (202) 208–2106 with the required accommodations.

Following the technical conference, all interested persons are invited to file initial and reply post-technical conference comments on the topics discussed during the technical conference, including the questions listed above. Commenters may reference material previously filed in this docket, including the technical conference transcript, but are encouraged to avoid repetition or replication of previous material. Initial comments are due on or before May 31, 2018; reply comments are due on or before June 15, 2018. Initial comments should not exceed 15 pages, and reply comments should not exceed 10 pages. The written comments will be included in the formal record of the proceeding, which, together with the record developed to date, will form the basis for further Commission action.

For Further Information, Please Contact Individuals Identified for Each Topic:

Technical Information: Laura Switzer, Office of Energy Markets Regulation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6231, *laura.switzer@ferc.gov*

Legal Information for Docket Nos. AD18–12–000 and EL17–45–000: Linda Kizuka, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8773, *linda.kizuka@ferc.gov*

Legal Information for Docket Nos. AD18–12–000 and ER18–370–000: Susanna Ehrlich, Office of the General Counsel, Federal Energy Regulatory

Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6260, *susanna.ehrlich@ferc.gov*

Logistical Information: Sarah McKinley, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8368, *sarah.mckinley@ferc.gov.*

Dated: April 10, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–07923 Filed 4–16–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP18–228–001.
Applicants: Rockies Express Pipeline LLC
Description: Compliance filing Compliance to RP18–228 Monthly FL&U Postings to be effective 4/19/2018.
Filed Date: 4/10/18.
Accession Number: 20180410–5148.
Comments Due: 5 p.m. ET 4/16/18.

Docket Numbers: RP18–694–000.
Applicants: Rockies Express Pipeline LLC..
Description: § 4(d) Rate Filing: Errata to RP18–228, Seneca Lateral to be effective 4/19/2018.
Filed Date: 4/10/18.
Accession Number: 20180410–5151.
Comments Due: 5 p.m. ET 4/16/18.

Docket Numbers: RP18–695–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: § 4(d) Rate Filing: Non-Conforming—Dalton (Cartersville, GA) to be effective 6/1/2018.
Filed Date: 4/10/18.
Accession Number: 20180410–5199.
Comments Due: 5 p.m. ET 4/23/18.

Docket Numbers: RP18–696–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Update Filing (TGS Apr 18) to be effective 4/11/2018.
Filed Date: 4/10/18.
Accession Number: 20180410–5221.
Comments Due: 5 p.m. ET 4/23/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 11, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–07998 Filed 4–16–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR18–20–000]

Notice of Petition for Declaratory Order; Marathon Pipe Line LLC, MPLX Ozark Pipe Line LLC

Take notice that on April 6, 2018, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2017), Marathon Pipe Line LLC and MPLX Ozark Pipe Line LLC filed a joint petition for a declaratory order seeking approval of certain terms and conditions in the transportation services agreement, related to a joint expansion project, all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on May 7, 2018.

Dated: April 10, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–07927 Filed 4–16–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP18–89–000]

Notice of Intent To Prepare an Environmental Assessment for the Proposed Empire Pipeline, Inc. Empire North Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Empire North Project involving construction and operation of facilities by Empire Pipeline, Inc. (Empire) in Tioga County, Pennsylvania and in Ontario, Yates, Schuyler, Chemung, and Steuben Counties, New York. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff

determine what issues they need to evaluate in the EA. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before May 10, 2018.

If you sent comments on this project to the Commission before the opening of this docket on February 16, 2018, you will need to file those comments in Docket No. CP18–89–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

Empire provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC website (*www.ferc.gov*).

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature on the Commission's website (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature on the Commission's website (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.*'' If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (CP18–89–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426.

Summary of the Proposed Project

Empire proposes to construct and operate gas compression facilities in Tioga County, Pennsylvania and in Ontario, New York. The Empire North Project would provide about 205 million cubic feet per day of incremental firm transportation capacity. The Empire North Project would consist of the following facilities:

- A new 21,000 horsepower (hp) compressor station in Jackson Township, Tioga County, Pennsylvania;
- a new 32,000 hp compressor station in the Town of Farmington, Ontario County, New York;
- modifications of the existing regulator valves and station piping and installation of metering facilities at the existing New Victor Regulator Station in Ontario County, New York;
- minor modifications to the existing Jackson Meter and Regulator Station in Jackson Township, Tioga County, Pennsylvania; and
- upgrading the maximum allowable operating pressure of the Empire Connector Pipeline (ECP) from 1,290 pounds per square inch gauge (psig) to 1,440 psig. The ECP is an existing 76.6-mile-long, 24-inch-diameter pipeline that runs from Victor, New York to Corning, New York in in Ontario, Yates, Schuyler, Chemung, and Steuben Counties, New York.

The general location of the project facilities is shown in appendix A.[1]

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE, Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

Land Requirements for Construction

Construction of the proposed facilities would disturb about 50.4 acres of land for the aboveground facilities. Following construction, Empire would maintain about 17.5 acres for permanent operation of the project's facilities; the remaining acreage would be restored and revert to former uses.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [2] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- water resources, fisheries, and wetlands;
- vegetation and wildlife;
- endangered and threatened species;
- cultural resources;
- land use;
- socioeconomics;
- air quality and noise;
- public safety; and
- cumulative impacts.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate with us in the preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Offices (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[4] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPOs as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If we publish and distribute the EA, copies of the EA will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the ''Document-less Intervention Guide'' under the ''e-filing'' link on the Commission's website. Motions to intervene are more fully described at *http://www.ferc.gov/resources/guides/how-to/intervene.asp.*

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.,* CP18–89). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Finally, public sessions or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: April 10, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–07924 Filed 4–16–18; 8:45 am]

BILLING CODE 6717–01–P

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[4] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting Notice

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: April 19, 2018, 10:00 a.m.

PLACE: Room 2C, 888 First Street NE, Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

*** Note**—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400.

For a recorded message listing items struck from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed on line at the Commission's website at *http://ferc.capitolconnection.org/* sing the eLibrary link, or may be examined in the Commission's Public Reference Room.

1042ND—MEETING

Regular Meeting

[April 19, 2018, 10:00 a.m.]

Item No.	Docket No.	Company
	Administrative	
A–1	AD18–1–000	Agency Administrative Matters.
A–2	AD18–2–000	Customer Matters, Reliability, Security and Market Operations.
A–3	AD06–3–000	Market Update.
	Electric	
E–1	RM17–2–000	Uplift Cost Allocation and Transparency in Markets Operated by Regional Transmission Organizations and Independent System Operators.
E–2	RM17–8–000	Reform of Generator Interconnection Procedures and Agreements.
E–3	RM17–11–000	Revised Critical Infrastructure Protection Reliability Standard CIP–003–7—Cyber Security—Security Management Controls.
E–4	Omitted.	
E–5	ER18–459–000, ER18–460–000	PJM Interconnection L.L.C. and Ohio Valley Electric Corporation.
E–6	ER17–1016–001	PJM Interconnection, L.L.C.
E–7	ER17–219–002	PacifiCorp.
E–8	ER17–2229–001	Southwest Power Pool, Inc.
	Hydro	
H–1	P–12715–013	Fairlawn Hydroelectric Company, LLC.
H–2	P–785–034	Consumers Energy Company.
H–3	P–14856–001	America First Hydro LLC.
	Certificates	
C–1	PL18–1–000	Certification of New Interstate Natural Gas Facilities.
C–2	CP17–469–000	WBI Energy Transmission, Inc.
C–3	CP16–20–001	High Island Offshore System, LLC.
C–4	CP14–497–001	Dominion Transmission, Inc.
C–5	CP15–77–001	Tennessee Gas Pipeline Company, L.L.C.
C–6	CP15–148–001	Tennessee Gas Pipeline Company, L.L.C.

Dated: April 12, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

A free webcast of this event is available through *http://ferc.capitolconnection.org/.* Anyone with internet access who desires to view this event can do so by navigating to *www.ferc.gov's* Calendar of Events and locating this event in the Calendar. The event will contain a link to its webcast. The Capitol Connection provides technical support for the free webcasts. It also offers access to this event via television in the DC area and via phone bridge for a fee. If you have any questions, visit *http://ferc.capitolconnection.org/* or contact Danelle Springer or David Reininger at 703–993–3100.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters, but will not be telecast through the Capitol Connection service.

[FR Doc. 2018–08082 Filed 4–13–18; 11:15 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–1485–009; ER10–1992–018; ER10–3230–009; ER10–3232–008; ER10–3237–009; ER10–3239–009; ER10–3240–009; ER10–3251–011; ER10–3253–009; ER13–1586–012; ER14–1777–008; ER14–2382–011; ER14–2871–011; ER15–110–010; ER15–2722–005; ER15–463–010; ER15–621–010; ER15–622–010; ER16–1129–004; ER16–1130–004; ER16–1131–004; ER16–1132–004; ER16–182–006; ER16–72–006; ER16–902–002; ER17–1574–001; ER17–1785–001; ER17–47–003; ER17–48–003; ER18–47–001

Applicants: Wheelabrator Baltimore, L.P., Wheelabrator Bridgeport, L.P., Wheelabrator Falls Inc., Wheelabrator Frackville Energy Company Inc., Wheelabrator North Andover Inc., Wheelabrator Portsmouth Inc., Wheelabrator Saugus Inc., Wheelabrator Shasta Energy Company Inc., Wheelabrator Westchester, L.P., Cameron Ridge, LLC, Cameron Ridge II, LLC, Coachella Wind, LLC, DifWind Farms Limited I, DifWind Farms Limited II, DifWind Farms Limited V, DifWind Farms LTD VI, EUI Affiliate LLC, Oak Creek Wind Power, LLC, ON Wind Energy LLC, Pacific Crest Power, LLC, Ridgetop Energy, LLC, San Gorgonio Westwinds II, LLC, San Gorgonio Westwinds II—Windustries, LLC, Terra-Gen Energy Services, LLC, Terra-Gen Mojave Windfarms, LLC, TGP Energy Management, LLC, Victory Garden Phase IV, LLC, Voyager Wind I, LLC, Voyager Wind II, LLC, VPI Enterprises, LLC.

Description: Notice of Change in Status of the ECP MBR Sellers.

Filed Date: 4/9/18.

Accession Number: 20180409–5338.

Comments Due: 5 p.m. ET 4/30/18.

Docket Numbers: ER14–1619–004.

Applicants: Cottonwood Energy Company LP.

Description: Compliance filing: Informational Filing Regarding Upstream Change in Control to be effective N/A.

Filed Date: 4/11/18.
Accession Number: 20180411–5076.
Comments Due: 5 p.m. ET 5/2/18.

Docket Numbers: ER14–2080–001.
Applicants: Louisiana Generating LLC.
Description: Compliance filing: Informational Filings Regarding Upstream Change in Control to be effective N/A.
Filed Date: 4/11/18.
Accession Number: 20180411–5075.
Comments Due: 5 p.m. ET 5/2/18.

Docket Numbers: ER15–502–002.
Applicants: Bayou Cove Peaking Power, LLC.
Description: Compliance filing: Informational Filings Regarding Upstream Change in Control to be effective N/A.
Filed Date: 4/11/18.
Accession Number: 20180411–5073.
Comments Due: 5 p.m. ET 5/2/18.

Docket Numbers: ER15–1136–002.
Applicants: Big Cajun I Peaking Power LLC.
Description: Compliance filing: Informational Filings Regarding Upstream Change in Control to be effective N/A.
Filed Date: 4/11/18.
Accession Number: 20180411–5074.
Comments Due: 5 p.m. ET 5/2/18.

Docket Numbers: ER18–1337–000.
Applicants: Interstate Power and Light Company.
Description: § 205(d) Rate Filing: IPL & MGE (Saratoga)—LBA Agreement to be effective 6/11/2018.
Filed Date: 4/10/18.
Accession Number: 20180410–5232.
Comments Due: 5 p.m. ET 5/1/18.

Docket Numbers: ER18–1338–000.
Applicants: Interstate Power and Light Company.
Description: § 205(d) Rate Filing: IPL & Turtle Creek—LBA Agreement to be effective 6/11/2018.
Filed Date: 4/11/18.
Accession Number: 20180411–5000.
Comments Due: 5 p.m. ET 5/2/18.

Docket Numbers: ER18–1339–000.
Applicants: California Independent System Operator Corporation.
Description: Compliance filing: 2018–04–10 Petition for Limited Tariff Waiver & Expedited Consideration Request to be effective N/A.
Filed Date: 4/11/18.
Accession Number: 20180411–5002.
Comments Due: 5 p.m. ET 5/2/18.

Docket Numbers: ER18–1340–000.
Applicants: South Carolina Electric & Gas Company.
Description: Contribution in Aid of Construction Agreement of South Carolina Electric & Gas Company.
Filed Date: 4/9/18.
Accession Number: 20180409–5339.
Comments Due: 5 p.m. ET 4/30/18.

Docket Numbers: ER18–1341–000.
Applicants: Virginia Electric and Power Company, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: VEPCO submits revisions to OATT, Attachment H–16C re: OPEB expense for 2017 to be effective 6/15/2018.
Filed Date: 4/11/18.
Accession Number: 20180411–5087.
Comments Due: 5 p.m. ET 5/2/18.

Docket Numbers: ER18–1343–000.
Applicants: Carolina Solar Power, LLC.
Description: Baseline eTariff Filing: Application and MBR Tariff to be effective 6/11/2018.
Filed Date: 4/11/18.
Accession Number: 20180411–5129.
Comments Due: 5 p.m. ET 5/2/18.

Take notice that the Commission received the following PURPA 210(m)(3) filings:

Docket Numbers: QM18–11–000.
Applicants: Cloverland Electric Cooperative.
Description: Application of Cloverland Electric Cooperative To Terminate Mandatory PURPA Purchase Obligation.
Filed Date: 4/10/18.
Accession Number: 20180410–5245.
Comments Due: 5 p.m. ET 5/8/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 11, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–07997 Filed 4–16–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–1321–000]

Calpine Mid-Merit II, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Calpine Mid-Merit II, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 1, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email

FERCOnlineSupport@ferc.gov. or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 11, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–08000 Filed 4–16–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–1310–000]

Wheelabrator Millbury Inc.; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Wheelabrator Millbury Inc.'s application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 1, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 11, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–07999 Filed 4–16–18; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9976–83–OAR]

Request for Nominations for Mobile Sources Technical Review Subcommittee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for nominations for Mobile Sources Technical Review Subcommittee (MSTRS).

SUMMARY: The U.S. Environmental Protection Agency (EPA) invites nominations from a diverse range of qualified candidates to be considered for appointment to its Mobile Sources Technical Review Subcommittee (MSTRS). Vacancies are anticipated to be filled by Fall, 2018. Sources in addition to this **Federal Register** Notice may also be utilized in the solicitation of nominees.

DATES: Nominations must be postmarked or emailed by May 22, 2018.

ADDRESSES: Submit nominations to: Courtney McCubbin, Designated Federal Officer, Office of Transportation and Air Quality, U.S Environmental Protection Agency (6401A), 1200 Pennsylvania Avenue NW, Washington, DC 20460. You may also email nominations with subject line MSTRS2018 to *mccubbin.courtney@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Courtney McCubbin, Designated Federal Officer, U.S. EPA; telephone: (202) 564–2436; email: *mccubbin.courtney@epa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The MSTRS is a federal advisory committee chartered under the Federal Advisory Committee Act (FACA), Public Law 92–463. The MSTRS provides the Clean Air Act Advisory Committee (CAAAC) with independent advice, counsel and recommendations on the scientific and technical aspects of programs related to mobile source air pollution and its control.

Through its expert members from diverse stakeholder groups and from its various workgroups, the subcommittee reviews and addresses a wide range of developments, issues and research areas such as emissions modeling, emission standards and standard setting, air toxics, innovative and incentive-based transportation policies, onboard diagnostics, heavy-duty engines, diesel retrofit, and fuel quality. The Subcommittee's website is at: *http://www.epa.gov/caaac/mobile-sources-technical-review-subcommittee-mstrs-caaac.*

Members are appointed by the EPA Administrator for three-year terms with the possibility of reappointment to a second term. The MSTRS usually meets two times annually and the average workload for the members is approximately 5 to 10 hours per month. EPA provides reimbursement for travel and other incidental expenses associated with official government business for members who qualify.

EPA is seeking nominations from representatives of nonfederal interests such as:

- Future transportation options and shared mobility interests
- Mobile source emission modeling interests
- Transportation and supply chain shippers
- Marine and inland port interests
- Environmental advocacy groups
- Community and/or environmental justice interests
- State and local government interests

EPA values and welcomes diversity. To obtain nominations of diverse candidates, EPA encourages nominations of women and men of all racial and ethnic groups.

In selecting members, we will consider technical expertise, coverage of broad stakeholder perspectives, diversity and the needs of the subcommittee.

The following criteria will be used to evaluate nominees:

- The background and experiences that would help members contribute to the diversity of perspectives on the committee (*e.g.,* geographic, economic, social, cultural, educational, and other considerations);
- Experience in policy engagement across a range of mobility source transportation topics;

• Experience working with future transportation options and shared mobility;
• Experience working with the modeling of mobile source emissions;
• Experience working with producers of passenger cars, engines and trucks, engine and equipment manufacturing;
• Experience working with fuel or renewable fuel producers;
• Experience working with oil refiners, distributors and retailers of mobile source fuels;
• Experience working with clean energy producers;
• Experience working with agricultural producers (corn and other crop products), distillers, processors and shippers of biofuels;
• Experience working with emission control manufacturers, catalyst and filter manufacturers;
• Experience working for State and local environmental agencies or State Air Pollution Control Agencies;
• Experience working for environmental advocacy groups;
• Experience working for environmental and/or community groups;
• Experience working with supply chain logistics and goods movement;
• Experience working with marine port interests;
• Experience in working at the national level on local governments issues;
• Demonstrated experience with environmental and sustainability issues;
• Executive management level experience with membership in broad-based networks;
• Excellent interpersonal, oral and written communication and consensus-building skills;
• Ability to volunteer time to attend meetings two times a year, participate in teleconference and webinar meetings, attend listening sessions with the Administrator or other senior-level officials, develop policy recommendations to the Administrator, and prepare reports and advice letters.

Nominations must include a resume and a short biography describing the professional and educational qualifications of the nominee, as well as the nominee's current business address, email address, and daytime telephone number. Interested candidates may self-nominate.

To help the Agency in evaluating the effectiveness of its outreach efforts, please tell us how you learned of this opportunity.

Please be aware that EPA's policy is that, unless otherwise prescribed by statute, members generally are appointed to three-year terms.

Dated: April 3, 2018.

Karl Simon,

Director, Transportation and Climate Division, Office of Transportation and Air Quality.

[FR Doc. 2018–08018 Filed 4–16–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[9976–94—Region 5]

Proposed Prospective Purchaser Agreement for the Manual Transmission of Muncie Site in Muncie, Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with the Prospective Purchaser Agreement, notice is hereby given of a proposed administrative settlement concerning the Manual Transmission of Muncie Site in Muncie, Indiana with the following Settling Party: Fourteen91 Loft, LLC. The settlement requires the Settling Party to, if necessary, execute and record a Declaration of Restrictive Covenant; provide access to the Site and exercise due care with respect to existing contamination. The settlement includes a covenant not to sue the Settling Parties pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act or the Resource Conservation and Recovery Act with respect to the Existing Contamination. Existing Contamination is defined as any hazardous substances, pollutants, or contaminants or Waste Material present or existing on or under the Property as of the Effective Date of the Settlement Agreement; any hazardous substances, pollutants, or contaminants or Waste Material that migrated from the Property prior to the Effective Date; and any hazardous substances, pollutants, or contaminants or Waste Material presently at the Site that migrates onto, on, under, or from the Property after the Effective Date.

For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at the EPA, Region 5, Records Center, 77 W Jackson Blvd., 7th Fl., Chicago, Illinois 60604. Commenters may request an opportunity for a public hearing in the affected area, in accordance with Section 7003(d) of RCRA.

DATES: Comments must be submitted on or before 30 days after publication in the **Federal Register**.

ADDRESSES: The proposed settlement is available for public inspection at the EPA, Region 5, Records Center, 77 W Jackson Blvd., 7th Fl., Chicago, Illinois 60604. A copy of the proposed settlement may be obtained from Peter Felitti, Assoc. Regional Counsel, EPA, Office of Regional Counsel, Region 5, 77 W Jackson Blvd., mail code: C–14J, Chicago, Illinois 60604. Comments should reference the Manual Transmission of Muncie Site, Muncie, Indiana and should be addressed to Peter Felitti, Assoc. Regional Counsel, EPA, Office of Regional Counsel, Region 5, 77 W Jackson Blvd., mail code: C–14J, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Peter Felitti, Assoc. Regional Counsel, EPA, Office of Regional Counsel, Region 5, 77 W Jackson Blvd., mail code: C–14J, Chicago, Illinois 60604.

SUPPLEMENTARY INFORMATION: The Settling Parties propose to acquire ownership of the former General Motors Corporation North American operation, at 1220 West 8th Street in Muncie, Indiana. The Site is one of the 89 sites that were placed into an Environmental Response Trust (the ''Trust'') as a result of the resolution of the 2009 GM bankruptcy. The Trust is administrated by Revitalizing Auto Communities Environmental Response.

Dated: April 3, 2018.

Douglas E. Ballotti,

Deputy Director, Superfund Division.

[FR Doc. 2018–08023 Filed 4–16–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1189]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction

Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before May 17, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov;* and to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain*, (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control Number: 3060–1189.

Title: Signal Boosters, Sections 1.1307(b)(1), 20.3, 20.21(a)(2), 20.21(a)(5), 20.21(e)(2), 20.21(e)(8)(I)(G), 20.21(e)(9)(I)(H), 20.21(f), 20.21(h), 22.9, 24.9, 27.9. 90.203, 90.219(b)(l)(I), 90.219(d)(5), and 90.219(e)(5).

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, Not for profit institutions and Individuals or household.

Number of Respondents and Responses: 632,595 respondents and 635,215 responses.

Estimated Time per Response: .5 hours-40 hours.

Frequency of Response: Recordkeeping requirement, On occasion reporting requirement and Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in 47 U.S.C. 154(I), 303(g), 303(r) and 332.

Total Annual Burden: 324,470 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: This information collection affects individuals or households; thus, there are impacts under the Privacy Act. However, the government is not directly collecting this information and the R&O directs carriers to protect the information to the extent it is considered Customer Proprietary Network Information (CPNI).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The Commission is seeking approval from the Office of Management and Budget (OMB) approval for a three year time period for this information collection requirements approved under this collection. The following information collection requirements are approved under this collection:

Labeling Requirements: Sections 20.21(a)(5), 20.21(f), 90.219(e)(5)—In order to avoid consumer confusion and provide consumers with needed information, the Commission adopted labeling requirements for Consumer and Industrial Signal Boosters. Consumer Signal Boosters must be labeled to identify the device as a ''consumer'' device and make the consumer aware that the device must be registered; may only be operated with the consent of the consumer's wireless provider; may only be operated with approved antennas and cables; and that E911 communications may be affected for calls served by using the device. Industrial Signal Boosters must include a label stating that the device is not a consumer device, is designed for installation by FCC licensees or a qualified installer, and the operator must have a FCC license or consent of a FCC licensee to operate the device. Accordingly, all signal boosters marketed on or after March 1, 2014, must include the advisories (1) in on-line point-of-sale marketing materials; (2) in any print or on-line owner's manual and installation instructions; (3) on the outside packaging of the device; and (4) on a label affixed to the device. Part 90 signal boosters marketed or sold on or after March 1, 2014, must include a label stating that the device is not a consumer device; the operator must have a FCC license or consent of a FCC licensee to operate the device; the operator must register Class B signal boosters; and unauthorized use may result in significant forfeitures.

Section 20.21(f)(1)(iv)(A)(2)—In order to ensure that consumers are properly informed about which devices are suitable for their use and how to comply with our rules, the Commission required that all Consumer Signal Boosters certified for fixed, in-building operation include a label directing consumers that the device may only be operated in a fixed, in-building location. The Verizon Petitioners state that this additional labeling requirement is necessary to

inform purchasers of fixed Consumer Signal Boosters that they may not lawfully be installed and operated in a moving vehicle or outdoor location. We recognize that our labeling requirement imposes additional costs on entities that manufacture Consumer Signal Boosters; however, on balance, we find that such costs are outweighed by the benefits of ensuring that consumers purchase appropriate devices. Accordingly, all fixed Consumer Signal Boosters, both Provider-Specific and Wideband, manufactured or imported on or after one year from the effective date of the rule change must include the following advisory (1) in on-line point-of-sale marketing materials, (2) in any print or on-line owner's manual and installation instructions, (3) on the outside packaging of the device, and (4) on a label affixed to the device: ''This device may be operated ONLY in a fixed location for in-building use.''

Section 1.1307(b)(1)—Radiofrequency (RF). This rule requires that a label is affixed to the transmitting antenna that provides adequate notice regarding potential RF safety hazards and references the applicable FCC-adopted limits for RF exposure. Provider Reporting Requirement: In order to facilitate review of wireless providers' behavior regarding Consumer Signal Boosters, the R&O requires that on March 1, 2015, and March 1, 2016, all nationwide wireless providers publicly indicate their status regarding consent for each Consumer Signal Booster that has received FCC certification as listed in a Public Notice to be released by the Wireless Telecommunications Bureau 30 days prior to each reporting date. For each listed Consumer Signal Booster, wireless providers should publicly indicate whether they (1) consent to use of the device; (2) do not consent to use of the device; or (3) are still considering whether or not they will consent to the use of the device.

Registration Requirements: Section 20.21(a)(2)—The rules require signal booster operators to register Consumer Signal Boosters, existing and new, with their serving wireless providers prior to operation. This is a mandatory requirement to continue or begin operation of a Consumer Signal Booster. The registration requirement will aid in interference resolution and facilitate provider control over Consumer Signal Boosters. The information collection contained in Section 20.21(a)(2) affects individuals or households; thus, there are impacts under the Privacy Act. However, the government is not directly collecting this information and the R&O directs carriers to protect the information to the extent it is considered Customer Proprietary Network Information (CPNI).

Section 20.21(h)—By March 1, 2014, all providers who voluntarily consent to the use of Consumer Signal Boosters on their networks must establish a free registration system for their subscribers. At a minimum, providers must collect (1) the name of the Consumer Signal Booster owner and/or operator, if different individuals; (2) the make, model, and serial number of the device; (3) the location of the device; and (4) the date of initial operation. Otherwise, the Commission permits providers to develop their own registration systems to facilitate provider control and interference resolution, providers should collect only such information that is reasonably related to achieving these dual goals. Wireless providers may determine how to collect such information and how to keep it up-to-date. Section 90.219(d)(5)—This rule requires operators of Part 90 Class B signal boosters to register these devices in a searchable on-line database that will be maintained and operated by the Wireless Telecommunications Bureau via delegated authority from the Commission. The Commission believes this will be a valuable tool to resolve interference should it occur.

Certification Requirements: Sections 20.3, 20.21(e)(2), 20.21(e)(8)(i)(G), 20.21(e)(9)(i)(H), 90.203—These rules, in conjunction with the R&O, require that signal booster manufacturers demonstrate that they meet the new technical specifications using the existing and unchanged equipment authorization application, including submitting a technical document with the application for FCC equipment authorization that shows compliance of all antennas, cables and/or coupling devices with the requirements of § 20.21(e). The R&O further provides that manufacturers must make certain certifications when applying for device certification. Manufacturers must provide an explanation of all measures taken to ensure that the technical safeguards designed to inhibit harmful interference and protect wireless networks cannot be deactivated by the user. The R&O requires that manufacturers of Provider-Specific Consumer Signal Boosters may only be certificated with the consent of the licensee so the manufacturer must certify that it has obtained such consent as part of the equipment certification process. The R&O also requires that if a manufacturer claims that a device will not affect E911 communications, the manufacturer must certify this claim during the equipment certification process. Note: The ''application for equipment'' certification requirements are met under OMB Control Number 3060–0057, FCC Form 731.

Antenna Kitting Documentation Requirement: Sections 20.21(e)(8)(i)(G), 20.21(e)(9)(i)(H)—The rules require that all consumer boosters must be sold with user manuals specifying all antennas and cables that meet the requirements of this section. Part 90 Licensee Consent Documentation Requirement: Section 90.219(b)(1)(i)—This rule requires that non-licensees seeking to operate part 90 signal boosters must obtain the express consent of the licensee(s) of the frequencies for which the device or system is intended to amplify. The rules further require that such consent must be maintained in a recordable format that can be presented to a FCC representative or other relevant licensee investigating interference.

Cross-reference to Other Rule Parts: Sections 22.9, 24.9, and 27.9—Operation of a consumer signal booster under Parts 22, 24, and 27 of the Commission's rules must also comply with section 20.21 of the Commission's rules, including all relevant information collections.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison, Office of the Secretary.

[FR Doc. 2018–08027 Filed 4–16–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Open Commission Meeting, Tuesday, April 17, 2018

April 10, 2018.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Tuesday, April 17, 2018 which is scheduled to commence at 10:30 a.m. in Room TW–C305, at 445 12th Street SW, Washington, DC.

Item No.	Bureau	Subject
1	Wireline Competition	Title: Protecting Against National Security Threats to the Communications Supply Chain Through FCC Programs (WC Docket No. 18–89).

Item No.	Bureau	Subject
		Summary: The Commission will consider a Notice of Proposed Rulemaking to ensure that universal service support is not used to purchase equipment or services from companies posing a national security threat to the integrity of communications networks or the communications supply chain.
2	Wireless Tele-Communications	Title: Auctions of Upper Microwave Flexible Use Licenses for Next-Generation Wireless Services; Competitive Bidding Procedures for Auctions 101 (28 GHz) and 102 (24 GHz) (AU Docket No. 18–85). Summary: The Commission will consider a Public Notice that would seek comment on the procedures for the auctions of Upper Microwave Flexible Use Service licenses in the 28 GHz and 24 GHz bands.
3	International	Title: Streamlining Licensing Procedures for Small Satellites (IB Docket No. 18–86). Summary: The Commission will consider a Notice of Proposed Rulemaking that proposes a new, alternative application process designed for a class of satellites referred to as ''small satellites.''
4	Wireline Competition	Title: Rural Call Completion (WC Docket No. 13–39). Summary: The Commission will consider a Report and Order and Further Notice of Proposed Rulemaking that will adopt new measures, and seek comment on others, to better tackle the problem of call completion and ensure that calls are completed to all Americans—including those in rural America.
5	Wireline Competition	Title: Regulation of Business Data Services for Rate-of-Return Local Exchange Carriers (WC Docket No. 17–144). Summary: The Commission will consider a Notice of Proposed Rulemaking to enable model-based rate-of-return carriers to elect incentive regulation for their lower-speed business data services offerings, and to remove ex ante pricing regulation for packet-based and higher-speed circuit-based offerings.
6	Media	Title: Cable Channel Lineup Requirements—Sections 76.1705 and 76.1700(a)(4) (MB Docket No. 18–92); Modernization of Media Regulation Initiative (MB Docket No. 17–105). Summary: The Commission will consider a Notice of Proposed Rulemaking proposing to eliminate the requirement that cable operators maintain a channel lineup at their local office and seeking comment on eliminating the requirement that certain cable operators make their channel lineup available via their online public inspection file.
7	Media	Title: Amendment of Section 73.624(g) of the Commission's Rules Regarding Submission of FCC Form 2100, Schedule G, Used to Report TV Stations' Ancillary or Supplementary Services (MB Docket No. 17–264); Modernization of Media Regulation Initiative (MB Docket No. 17–105). Summary: The Commission will consider a Report and Order that would revise Section 73.624(g) of its rules to reduce broadcaster reporting obligations relating to the provision of ancillary or supplementary services.

* * * * *

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500; TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the internet from the FCC Live web page at *www.fcc.gov/live.*

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the internet. To purchase these services, call (703) 993–3100 or go to *www.capitolconnection.gmu.edu.*

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2018–08028 Filed 4–16–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0031]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with

a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before June 18, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

Control Number: 3060–0031.

Title: Application for Consent to Assignment of Broadcast Station Construction Permit or License, FCC Form 314; Application for Consent to Transfer Control of Entity Holding Broadcast Station Construction Permit or License, FCC Form 315; Section 73.3580, Local Public Notice of Filing of Broadcast Applications.

Form Number: FCC Forms 314 and 315.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, local or Tribal government.

Number of Respondents and Responses: 4,840 respondents and 12,880 responses.

Estimated Time per Response: 0.084 to 6 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in Sections 154(i), 303(b) and 308 of the Communications Act of 1934, as amended.

Total Annual Burden: 18,670 hours.

Total Annual Cost: $52,519,656.

Privacy Impact Assessment(s): No impacts.

Nature and Extent of Confidentiality: There is no need for confidentiality and respondents are not being asked to submit confidential information to the Commission.

Needs and Uses: FCC Form 314 and the applicable exhibits/explanations are required to be filed when applying for consent for assignment of an AM, FM, LPFM or TV broadcast station construction permit or license. In addition, the applicant must notify the Commission when an approved assignment of a broadcast station construction permit or license has been consummated.

FCC Form 315 and applicable exhibits/explanations are required to be filed when applying for transfer of control of an entity holding an AM, FM, LPFM or TV broadcast station construction permit or license. In addition, the applicant must notify the Commission when an approved transfer of control of a broadcast station construction permit or license has been consummated.

Due to the similarities in the information collected by these two forms, OMB has assigned both forms OMB Control Number 3060–0031.

47 CFR 73.3580 requires local public notice in a newspaper of general circulation published in the community in which a station is located of the filing of all applications for transfer of control or assignment of the license/permit. This notice must be completed within 30 days of the tendering of the application. This notice must be published at least twice a week for two consecutive weeks in a three-week period. A copy of this notice and the application must be placed in the station's public inspection file along with the application, pursuant to Section 73.3527. Additionally, an applicant for transfer of control of a license must broadcast the same notice over the station at least once daily on four days in the second week immediately following the tendering for filing of the application.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison, Office of the Secretary.

[FR Doc. 2018–08026 Filed 4–16–18; 8:45 am]

BILLING CODE 6712–01–P

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

DEPARTMENT OF THE TREASURY

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System (''Board'') and Departmental Offices, Department of the Treasury (''Treasury'') (collectively, the ''Agencies'').

ACTION: Joint notice, request for comment.

SUMMARY: The Agencies invite comment on a proposal to extend for three years, without revision, the mandatory recordkeeping requirements associated with a joint rule implementing the Unlawful internet Gambling Enforcement Act of 2006 (the ''Act'').

DATES: Comments must be submitted on or before June 18, 2018.

ADDRESSES: Interested parties are invited to submit written comments to either or both of the Agencies. All comments, which should refer to the Office of Management and Budget (OMB) control numbers, will be shared between the Agencies. Direct all written comments as follows:

Board: You may submit comments, identified by OMB control no. *7100–0317,* by any of the following methods:

- *Agency Website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include OMB number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 3515, 1801 K Street NW (between 18th and 19th Streets NW), Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Treasury: You may submit comments, identified by OMB control no. *1505–0204,* by regular mail to Martha Chacon, Staff Assistant, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Room 2000, Washington, DC 20220. In addition, comments may be sent by fax to (202) 622–1974, or by electronic mail to *Martha.Chacon-Ospina@treasury.gov.* In general, the Treasury will make all comments available in their original format, including any business or personal

information provided such as names, addresses, email addresses, or telephone numbers, for public inspection and copying in the Treasury library, 1500 Pennsylvania Avenue NW, Washington, DC 20220, on official business days between the hours of 10 a.m. and 5 p.m. You can make an appointment to inspect comments by calling (202) 622–0990. All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should only submit comments that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files, once approved. Requests for additional information or a copy of the collection may be obtained by contacting:

Board: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

Treasury: Steven D. Laughton, Assistant General Counsel (Banking and Finance), (202) 622–8413, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Room 2001, Washington, DC 20220.

SUPPLEMENTARY INFORMATION:

Request for Comment on Information Collection Proposal

The Agencies invite public comment on the following information collection. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;

b. The accuracy of the Federal Reserve's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Comments submitted in response to this notice will be shared between the Agencies. All comments received, including attachments and other supporting materials, are part of the public record and will be included in the submission to the Office of Management and Budget (OMB).

Title: Prohibition on Funding of Unlawful internet Gambling.

OMB Control Numbers:

Board: 7100–0317.

Treasury: 1505–0204.

General Description of Report: On November 18, 2008, the Agencies published a joint notice of final rulemaking in the **Federal Register** (73 FR 69382) adopting a rule on a prohibition on the funding of unlawful internet gambling pursuant to the Act. Identical sets of the final joint rule with identically numbered sections were adopted by the Board and the Treasury within their respective titles of the Code of Federal Regulations (12 CFR part 233 for the Board and 31 CFR part 132 for the Treasury). The compliance date for the joint rule was June 1, 2010 (74 FR 62687). The collection of information is set out in sections 5 and 6 of the joint rule.[1] Section 5 of the joint rule, as required by the Act, requires all non-exempt participants in designated payment systems to establish and implement written policies and procedures reasonably designed to identify and block or otherwise prevent or prohibit transactions in connection with unlawful internet gambling. Section 6 of the joint rule provides non-exclusive examples of policies and procedures deemed by the Agencies to be reasonably designed to identify and block or otherwise prevent or prohibit transactions restricted by the Act.

Affected Public: Businesses or other for-profit and not-for-profit organizations.

Respondent Burden

For the purpose of estimating burden and accounting for it with OMB, the total number of depository institutions listed for each Agency includes the number of entities regulated by the Agency and half of the remaining depository institutions and third-party processors. Each Agency is also accounting for the burden for half of the card system operators and money transmitting business operators to which the Agencies estimate the final rule applies.

Board

Estimated number of recordkeepers: 2,628 depository institutions, 2,839 credit unions, 7 card system operators, 43 money transmitting business operators, and 3 new or de novo institutions.

Estimated average annual burden hours per recordkeeper: Ongoing annual burden of 8 hours per recordkeeper for depository institutions, credit unions, card system operators, and money transmitting business operators. One-time burden of 100 hours for new or de novo institutions.

Estimated frequency: Annually.

Estimated total annual recordkeeping burden: Ongoing burden, 44,436 hours and one-time burden, 300 hours.

Treasury

Estimated number of recordkeepers: 3,146 depository institutions, 2,839 credit unions, 7 card system operators, 43 money transmitting business operators, and 3 new or de novo institutions.

Estimated average annual burden hours per recordkeeper: Ongoing annual burden of 8 hours per recordkeeper for depository institutions, credit unions, card system operators, and money transmitting business operators. One-time burden of 100 hours for new or de novo institutions.

Estimated frequency: Annually.

Estimated total annual recordkeeping burden: Ongoing burden, 48,580 hours and one-time burden, 300 hours.

Board of Governors of the Federal Reserve System on March 23, 2018.

Ann E. Misback,

Secretary of the Board.

Dated: March 29, 2018.

By the Department of the Treasury.

Spencer W. Clark,

Clearance Officer.

[FR Doc. 2018–07945 Filed 4–16–18; 8:45 am]

BILLING CODE 6210–01–P; 4810–25–P

[1] Section 802 of the Act requires the agencies to prescribe joint regulations requiring each designated payment system, and all participants in such systems, to identify and block or otherwise prevent or prohibit restricted transactions through the establishment of policies and procedures reasonably designed to identify and block or otherwise prevent or prohibit the acceptance of restricted transactions.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project ''Outcome Measure Repository (OMR).''

This proposed information collection was previously published in the **Federal Register** on January 29, 2018, and allowed 60 days for public comment. AHRQ received no substantive comments from the public. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by May 17, 2018.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Outcome Measure Repository

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites public comment on this proposed information collection. In accordance with the agency's mission, AHRQ developed the Outcome Measure Repository (OMR), a web-based database with the purpose of providing a readily available public resource that includes definitions of outcome measures associated with patient registries. The information being collected in each OMR record will be visible to the public and readily available for public use.

This effort is in alignment the AHRQ Registry of Patient Registries (RoPR), which provides a central point of collection for information about all patient registries in the United States. The RoPR furthers AHRQ's goals to enhance the description of the quality, appropriateness, and effectiveness of health services, and patient registries in particular, in a more readily available, central location by enhancing patient registry information, extracted from *ClinicalTrials.gov* or modeled based on the *ClinicalTrials.gov* data elements.

The development of the OMR continues these efforts, and aims to achieve the following objectives:

(1) Provide a searchable database of outcome measures used in patient registries in the United States to promote collaboration, reduce redundancy, and improve transparency;

(2) Facilitate the use of standardized data elements and outcome measures; and

(3) Facilitate the identification of potential areas of harmonization.

The OMR system will be linked to RoPR in two key ways. First, users entering registry information in the RoPR system will be able to associate OMR measure records with the RoPR registry records, and, measure stewards listing a measure record in the OMR system will be able to associate the measure with an existing patient registry in RoPR. Second, users will be able to access both databases with a single account (*i.e.,* users with a RoPR account will be able to log in/access the OMR using that account, and vice versa).

This study is being conducted by AHRQ through its contractor, L&M Policy Research and subcontractors Truven Health Analytics, an IBM Company, and OM1, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the outcomes, cost, cost-effectiveness, and use of health care services and access to such services, and with respect to health statistics and database development. 42 U.S.C. 299a(a)(3) and (8).

Method of Collection

To achieve the three objectives of this project, outcome measures and related sub-elements from measure stewards who populate the OMR database system will be collected.

Users of the OMR will primarily fall into two types: Those stewarding a registry who will provide information on the data they collect in their registry, and those who will search for information about how a particular type of outcome measure is collected within patient registries. For the OMR to succeed, the first group of users must be able to enter information into the system easily and efficiently. The second group of users must be able to find sufficient information efficiently on outcome measures to identify items for use in their own registry or research. Meeting the needs of both sets of users is an important consideration in the design of the OMR.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to contribute to the OMR.

Based on the number of respondents submitting RoPR records in 2016 (65 respondents), it is expected that a similar number of stakeholders (approximately 70 respondents) will provide measure information in the OMR on an annual basis.

All users will complete required fields on the ''Measure Profile'' form. Some users may also choose to complete the ''Sub-Element Profile'' form for one or more sub-elements associated with a given measure although this is not required. The number of sub-elements for a given measure is expected to vary widely. Many users may not provide sub-element information, while others may include five or more. It is expected that on average, measure stewards will enter information for two sub-elements.

In September 2017, Truven Health Analytics consulted with several stakeholders and used a sample of existing measure definitions to estimate the time required to enter all OMR fields. The sample included measures representing a range of depth and complexity. For example, one measure record contained no sub-element information, only required fields, and short responses to open text fields (*e.g.,* title and description). Another record contained two sub-elements, all optional fields, and longer responses to open text fields.

As a result of the knowledge gained during these processes, it is estimated that it will take users 16 minutes, on average, to enter manually the additional fields added through the self-registration process (an average of 12 minutes to complete the Measure Profile form and 4 minutes to complete two Sub-Element Profile sub-forms). If 70 respondents complete the Measure Profile form and two Sub-Element Profile sub-forms, the estimated annualized burden would be 18.7 hours total.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Minutes per response	Total burden hours
OMR Measure Profile/Sub-Element Profile	70	1	16/60	18.7
Total	70	1	16/60	18.7

Exhibit 2 shows the estimated cost burden associated with the respondent's time to participate in the OMR. The total cost burden to respondents is estimated at an average of $711.72 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate †	Total cost burden
OMR Measure Profile/Sub-Element Profile	70	18.7	$38.06	$711.72
Total	70	18.7	38.06	711.72

* Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29–0000. National Compensation Survey: Occupational Wages in the United States May 2016, "U.S. Department of Labor, Bureau of Labor Statistics." Available at: *https://www.bls.gov/oes/current/oes290000.htm.*

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Karen Migdail,

Chief of Staff.

[FR Doc. 2018–08009 Filed 4–16–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–0792; Docket No. CDC–2018–0031]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled, Environmental Health Specialists Network (EHS–NET) Program Generic Package. The goal of this food safety research program is to collect data in retail food establishments that will identify and help to understand environmental factors (*e.g.,* manager food safety certification, implementation of food safety practices, etc.) associated with retail-related foodborne illness and outbreaks.

DATES: CDC must receive written comments on or before June 18, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0031 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new

proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Environmental Health Specialists Network (EHS–NET) Program Generic Package (OMB Control Number 0920–0792; expiration date 9/30/2018)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), is requesting a three-year Office of Management and Budget approval for the revision Generic Information Collection plan titled the *Environmental Health Specialists (EHS-Net).*

The EHS-Net program focuses on identifying the environmental causes of foodborne illness. In October 2008, OMB approved the EHS-Net program generic information collection plan. OMB approved renewal collections in both 2012 and 2015. To date, EHS-Net has conducted five individual data collections under this plan.

CDC seeks a revision to conduct information collections through 2021. The CDC plans to revise the plan in the following ways:

(1) The burden hours have increased to allow for additional statistical designs. The number of restaurants per site (8 EHS-Net sites, which has remained the same) has increased from 47 to 50 restaurants (totaling 400 restaurants); the sample size was increased to detect a greater odds ratio and establish a stronger power.

(2) The number of respondents has increased to gather additional food worker responses per establishment. Collecting data from additional food workers (increased to 10 food workers per restaurant from 1 food worker per restaurant, totaling 4,000 food workers) will help minimize the potential bias of only having one worker represent all of food workers in a given establishment. Additionally, going forward the restaurant observation data collection by the health department (HD) staff will also be included in the burden table.

(3) We expect to conduct up to three studies in a 5-year cooperative period; based on a more accurate study schedule in a 5-year EHS-Net cooperative agreement. Therefore, due to an increase in the number of restaurants, food workers interviews and addition of restaurant observation activity the estimated annual burden hours expected to increase from 295 to 1,777 annual hours.

The goal of this information collection is to improve food safety and reduce foodborne illness, which supports the U.S. Department of Health and Human Services' Healthy People 2020 Goal. Reducing foodborne illness first requires identification and understanding of the environmental factors that cause these illnesses. We need to know how and why food becomes contaminated with foodborne illness pathogens. This information can then be used to determine effective food safety prevention methods. Ultimately, these actions can lead to increased regulatory program effectiveness and decreased foodborne illness. The purpose of the information collection is to gather data that will help us identify and understand environmental factors associated with foodborne illness. Specifically, the information will be used to:

(a) Describe retail food establishment food handling and food safety practices and manager/worker and establishment characteristics,

(b) Determine how retail food establishment and worker characteristics are related to food handling and food safety practices.

The program Environmental Health Specialists Network (EHS-Net), conducted by a collaborative project of CDC, Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and local and state sites.

Environmental factors associated with foodborne illness include both food safety practices (*e.g.,* inadequate cleaning practices) and the factors in the environment associated with those practices (*e.g.,* worker and retail food establishment characteristics). To understand these factors, we need to continue to collect data from those who prepare food (*i.e.,* food workers) and on the environments in which the food is prepared (*i.e.,* retail food establishment kitchens). Thus, data collection methods for this generic information collection plane include: (1) Screener; (2) manager and food worker interviews/surveys; and (3) observation of kitchen/restaurant environments. These methods allow data collection on food safety practices and environmental factors associated with those practices.

For each data collection, CDC will collect data in approximately 50 retail food establishments per site. Thus, there will be approximately 400 establishments per data collection (an estimated 8 sites with 50 establishments).

The total estimated annual burden for each data collection will be 1,777 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Managers	EHS-Net Manager Recruiting Script	889	1	3/60	44
Managers	EHS-Net Manager Informed Consent and Interview.	400	1	30/60	200

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Food Workers	EHS-Net Food Worker Recruiting Screener, Informed Consent and Interview.	4,000	1	20/60	1,333
HD staff	EHS-Net Restaurant Observation	400	1	30/60	200
Total					1,777

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–08007 Filed 4–16–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3357–PN]

Medicare and Medicaid Program; Application From DNV GL—Healthcare (DNV GL) for Continued Approval of Its Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with request for comment.

SUMMARY: This proposed notice acknowledges the receipt of an application from DNV GL—Healthcare for continued recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs. The statute requires that we publish, within 60 days of receipt of an organization's complete application, a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 17, 2018.

ADDRESSES: In commenting, refer to file code CMS–3357–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3357–PN, P.O. Box 8016, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3357–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Karena Meushaw (410) 786–6609, Patricia Chmielewski, (410) 786–6899 or Monda Shaver, (410) 786–3410.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital, provided that certain requirements are met. Section 1861(e) of the Social Security Act (the Act), establishes distinct criteria for facilities seeking designation as a hospital. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 482 specify the minimum conditions that a hospital must meet to participate in the Medicare program.

Generally, to enter into an agreement, a hospital must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 482 of our regulations. Thereafter, the hospital is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. There is an alternative; however, to surveys by state agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide the Centers for Medicare and Medicaid Services (CMS) with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.5. The regulations at § 488.5(e)(2)(i) require accrediting organizations to reapply for continued approval of its accreditation program every 6 years or

sooner as determined by CMS. DNV GL—Healthcare (DNV GL) current term of approval for their hospital accreditation program expires September 26, 2018.

II. Provisions of the Proposed Notice

A. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of DNV GL's request for continued approval of its hospital accreditation program. This notice also solicits public comment on whether DNV GL's requirements meet or exceed the Medicare conditions of participation (CoPs) for hospitals.

B. Evaluation of Deeming Authority Request

DNV GL submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its hospital accreditation program. This application was determined to be complete on February 28, 2018. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of DNV GL will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of DNV GL's standards for hospitals as compared with CMS' hospital CoPs.
- DNV GL's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of DNV GL's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ DNV GL's processes and procedures for monitoring a hospital found out of compliance with the DNV GL's program requirements. These monitoring procedures are used only when the DNV GL identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the state survey agency monitors corrections as specified at § 488.9(c).

++ DNV GL's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ DNV GL's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of DNV GL's staff and other resources, and its financial viability.

++ DNV GL's capacity to adequately fund required surveys.

++ DNV GL's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ DNV GL's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

C. Notice Upon Completion of Evaluation

Upon completion of our evaluation, including evaluation of public comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: April 9, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–07982 Filed 4–16–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2294]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Fresh Empire Campaign on Tobacco

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by May 17, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0788. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed

collection of information to OMB for review and clearance.

Evaluation of the Food and Drug Administration's 'Fresh Empire' Multicultural Youth Tobacco Prevention Campaign

OMB Control Number 0910–0788—Extension

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing a youth-targeted public education campaign ('Fresh Empire') to help prevent tobacco use among multicultural youth and thereby reduce the public health burden of tobacco. The campaign features events, advertisements on television and radio and in print, digital communications including social media, and other forms of media.

Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions. Comprehensive evaluation of FDA's multicultural public education campaign will be used to document whether the intended audience is aware of and understands campaign messages, and whether campaign exposure influences specific cognitive outcomes related to tobacco use that are targeted by the campaign.

FDA is in the process of evaluating the effectiveness of its multicultural youth tobacco prevention campaign through an outcome evaluation study that follows the multiple, discrete waves of media advertising planned for the campaign. All information collected is integral to that evaluation.

FDA's *Fresh Empire* youth tobacco public education campaign aims to reduce tobacco use among youth who affiliate with a hip-hop peer crowd, predominantly among African American, Hispanic, and Asian/Pacific Islander youth. The outcome evaluation of the campaign consists of a pre-test survey of youth aged 12 to 17 before campaign launch followed by a series of post-test surveys beginning approximately 6 months after the campaign launch. The post-test surveys are conducted among youth who participated in one or more surveys (the embedded longitudinal cohort) and new participants who are recruited to make up for attrition. Eligible youth were initially 12 to 17 years old and influenced by the hip-hop peer crowd. Youth in the embedded longitudinal cohort may reach the age of 18 over the course of the evaluation.

To date, the pre-test and three post-test surveys have been conducted. Information has been collected about youth awareness of and exposure to campaign events and advertisements and about tobacco-related knowledge, attitudes, beliefs, intentions, and use. Information has also been collected on demographic variables including age, sex, race/ethnicity, grade level, and primary language.

All information is voluntarily provided and is being collected through in-person and web-based questionnaires. Youth respondents were recruited from two sources: (1) A sample drawn from 30 U.S. media markets gathered using an address-based postal mail sampling of U.S. households for the outcome evaluation, and (2) targeted social media (*e.g.,* Facebook, Instagram).

This study is being conducted in support of the provisions of the Tobacco Control Act that require FDA to protect the public health and to educate the population about the risks and potential risks of tobacco use. The information being collected is necessary to inform FDA's efforts towards these goals and to measure the effectiveness and public health impact of the campaign. Data from the outcome evaluation are being used to estimate awareness of and exposure to the campaign among youth in target markets where the campaign is active. Data are also being used to examine statistical associations between exposure to the campaign and subsequent changes in specific outcomes of interest, which include knowledge, attitudes, and beliefs related to tobacco use.

FDA requests OMB approval to extend OMB approval of the evaluation of FDA's multicultural youth tobacco public education campaign and to add two additional waves of data collection with existing youth in the study. To accommodate these two additional surveys, FDA requests approval to increase the number of burden hours under the existing control number. The fourth post-test survey will begin in July 2018. The fifth post-test survey will begin in February 2019. As was done in earlier post-test surveys, new youth will be recruited to participate to make up for attrition.

A total of 2,100 youth will voluntarily complete questionnaires for the fourth post-test survey, and the same number will complete questionnaires for the fifth post-test survey. These respondents will include existing youth who have participated in one or more surveys previously (''Longitudinal Cohort'') and new youth recruited via a mail-based screener or social media ads (''Cross-Sectional Refresher Sample''). Based on earlier response rates and longitudinal respondents aging out of the eligibility criteria (over the age of 18), we expect to need to recruit a larger number of cross-sectional respondents than in previous waves. We estimate that approximately 600 longitudinal youth and 1,500 cross-sectional youth will voluntarily participate in each of the fourth and fifth post-test surveys. With an estimated burden of 45 minutes per respondent, this adds 450 hours for longitudinal respondents and 1,125 hours for cross-sectional respondents for each of the fourth and fifth post-test evaluation surveys.

A mail-based screener was one of the methods used to identify eligible youth for the pre-test survey. This method will be used during the fourth post-test survey to recruit new youth aged 12 to 17 to ensure that the sample composition is similar across rounds of data collection. As was done during the pre-test survey, parents or guardians will be asked to provide consent and their contact information on this form. For the fourth post-test survey, the 5-minute youth screener and the 1-minute parental consent will be completed by 9,869 households for a total of 822 burden hours for youth and an additional 164 hours for the parents or guardians. This method will not be used during the fifth post-test survey, for which new participants will be recruited only via social media.

We will continue to recruit new youth through social media (*e.g.,* Facebook, Instagram) as a secondary strategy to recruit youth aged 13 to 17. An online version of the screener described above will continue to be used to identify eligible youth. The screener will take 5 minutes to complete and will be taken by an additional 4,000 youth during each of the fourth and fifth post-test surveys, for a total of 8,000 additional youth respondents and 666 total additional burden hours. The new total number of voluntary participants for the youth online post-test screener will be 32,000 and the total burden will be 2,666 hours. This includes the originally approved 24,000 participants and 2,000 burden hours.

As was done previously, eligible youth aged 13 to 14 who complete the

online screener will be asked to provide their parents' or guardians' contact information to provide parental consent for the main survey. The process of parents and guardians providing consent for eligible youth will take approximately 1 minute. For the fourth and fifth post-test surveys, we estimate that an additional 700 adults will be contacted to provide consent for eligible youth for a total of 11 additional burden hours. Added to the original 6,000 parents and 100 burden hours, the total number of parental online screeners and consents will be 6,700 and the total burden will be 111 hours.

With these additions, the estimated number of voluntary respondents/responses for all waves of data collection for the study is 107,743, and the total burden is estimated at 15,135 hours—an estimated increase of 4,813 hours from the last approval.

In the **Federal Register** of December 26, 2017 (82 FR 61003), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however, this comment was not PRA related.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Youth Mail screener-outcome survey	23,685	1	23,685	0.0833 (5 minutes)	1,973
Cross-Sectional Youth Refresher Sample, Post-test and assent/consent process-outcome surveys 1–5.	4,920	1	4,920	0.75 (45 minutes)	3,690
Youth Pre-test and assent/consent process-outcome survey.	2,194	1	2,194	0.50 (30 minutes)	1,097
Longitudinal Youth Cohort, Post-test and assent/consent process-outcome surveys 1–5.	6,039	1	6,039	0.75 (45 minutes)	4,530
Youth Online screener-outcome survey	40,000	1	40,000	0.0833 (5 minutes)	3,332
Adult parental permission process-outcome survey	30,905	1	30,905	0.0166 (1 minute)	513
Total	107,743				15,135

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07971 Filed 4–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0913]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 513(g) Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 17, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0705. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

513(g) Request for Information

OMB Control Number 0910–0705—Extension

This information collection supports Agency regulations and accompanying guidance. Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining the Agency's views about the classification and regulatory requirements that may be applicable to a particular device. Section 513(g) provides that, within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device. Regulations governing medical device classification procedures are codified under 21 CFR part 860.

The guidance document entitled ''FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff'' establishes procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA's responses to 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act.

Relatedly, the FD&C Act, as amended by the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), requires FDA to collect user fees for 513(g) requests for information. The guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information'' assists FDA staff and regulated industry by describing the user fees associated with 513(g) requests. The Medical Device User Fee Cover Sheet (Form FDA 3601), which accompanies the supplemental material described in this information collection is approved under OMB control number 0910–0511.

In the **Federal Register** of November 21, 2017 (82 FR 55381) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received in response to the notice.

We therefore retain the currently approved burden estimate for the information collection, which is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDRH 513(g) requests	114	1	114	12	1,368
CBER 513(g) requests	4	1	4	12	48
Total					1,416

[1] There are no capital costs of operating and maintenance costs associated with this collection off information.

Respondents to the collection of information are mostly device manufacturers; however, anyone may submit a 513(g) request for information. The total number of annual responses is based on the average number of 513(g) requests received each year by the Agency.

Dated: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07980 Filed 4–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0524]

Listing of Ingredients in Tobacco Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a revised final guidance for industry entitled ''Listing of Ingredients in Tobacco Products.'' The revised guidance document is intended to assist persons making tobacco product ingredient submissions to FDA as required by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: The announcement of the guidance is published in the **Federal Register** on April 17, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2009–D–0524 for ''Listing of Ingredients in Tobacco Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the revised draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Katherine Collins or Deirdre Jurand, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a revised guidance for industry entitled ''Listing of Ingredients in Tobacco Products.'' The revised guidance document is intended to assist persons making tobacco product ingredient submissions to FDA as required by the Tobacco Control Act.

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate given the requirement that ingredient listing submissions be submitted by May 8, 2018 (§ 10.115(g)(2)). We made this determination because FDA needs to timely communicate that the guidance presents a less burdensome policy that is consistent with the public health and clarifies ways in which tobacco product manufacturers and importers can submit ingredient listing submissions as required by section 904(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387d(a)(1)). Although this guidance document is immediately effective, it remains subject to comment in accordance with FDA's GGP regulation.

The Tobacco Control Act, enacted on June 22, 2009, amends the FD&C Act and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health (Pub. L. 111–31, 123 Stat. 1776). Among its many provisions, the Tobacco Control Act added section 904 to the FD&C Act, establishing requirements for tobacco product ingredient submissions.

II. Significance of Guidance

This revised guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on listing of ingredients in tobacco products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This revised guidance refers to previously approved collections of information found in FDA regulations. The revised draft guidance includes information and recommendations for how to provide ingredient listing submissions for tobacco products. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in section 904(a)(1) of the FD&C Act have been approved under OMB control number 0910–0650.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the revised guidance at either *https://www.regulations.gov* or *https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07973 Filed 4–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0001]

Advisory Committees; Filing of Closed Meeting Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the Agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2017.

ADDRESSES: Copies are available at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. You also may access the docket at *https://www.regulations.gov* for the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2017. Insert the docket number found in brackets in the heading of this document at *https://www.regulations.gov* into the ''Search'' box, clear filter under Document Type (left side of screen), and check ''Supporting and Related Material,'' then Sort By Best Match (from the drop-down menu; top right side of screen), ''ID Number (Z–A)'' or Sort By Best Match (from the drop-down menu) ''Title (A–Z),'' also found in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Russell Fortney, Director, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1068.

SUPPLEMENTARY INFORMATION: Under section 10(d) of the Federal Advisory Committee Act (5 U.S.C. app.) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2016, through September 30, 2017:

Center for Biologics Evaluation and Research:

Allergenic Products Advisory

Committee
Blood Products Advisory Committee
National Center for Toxicological Research:
Science Board to the National Center for Toxicological Research
Center for Drug Evaluation and Research:
Joint Meetings of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee
Drug Safety and Risk Management Advisory Committee

Annual Reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday, at:

(1) The Library of Congress, Madison Building, Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE, Rm. 133, Washington, DC 20540; and

(2) Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07981 Filed 4–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1203]

Pilot Meetings Program for Model-Informed Drug Development Approaches

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The sixth iteration of the Prescription Drug User Fee Act (PDUFA VI), incorporated as part of the FDA Reauthorization Act of 2017 (FDARA), highlights the goal of advancing model-informed drug development (MIDD). The Food and Drug Administration (FDA or Agency) is announcing a pilot program that affords sponsors or applicants who are selected for participation the opportunity to meet with Agency staff to discuss MIDD approaches in medical product development. Meetings under the pilot program will be conducted by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) during fiscal years 2018 to 2022. This pilot program is being conducted to fulfill FDA's performance commitment under PDUFA VI. For this pilot program, MIDD is defined as the application of exposure-based, biological, and/or statistical models derived from preclinical and clinical data sources to address drug development and/or regulatory issues (see Supplementary Information, I. Background, and II. Eligibility and Selection for Participation of this notice). For each approved proposal, the pilot program consists of two meetings between sponsors or applicants and the relevant center and will provide an opportunity for drug developers and FDA to discuss the application of MIDD approaches to the development and regulatory evaluation of medical products in development.

DATES: FDA will accept requests to participate in the program on a continuous basis beginning on April 17, 2018 through June 15, 2022. See section III of this notice for instructions about how to request participation in the pilot program. Meeting-granted and -denied decisions will be made the last 2 weeks of each quarter of the fiscal year based on submissions received to date. Requesters will receive a meeting-granted or -denied notification the first week of the new quarter.

The pilot program meetings will begin in Q4 of FY 2018 (July 1–September 30, 2018), and run through Q4 of FY 2022 (September 30, 2022). Proposals not selected for a given quarter will be so notified by the Agency. Sponsors who are not chosen to participate in the pilot program may seek Agency interaction through existing channels (*e.g.,* Type C meeting requests, critical path innovation meetings).

ADDRESSES: Comments about this pilot program can be submitted until May 17, 2018. You may submit comments about the MIDD pilot meetings program as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–1203 for ''Pilot Meetings Program for Model-Informed Drug Development Approaches.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

FOR FURTHER INFORMATION CONTACT:

CDER: Yvonne Knight, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2142, Silver Spring, MD 20993–0002, 301–796–2133, *Yvonne.Knight@fda.hhs.gov,* with the subject line ''MIDD Pilot Meetings Program for CDER.''

CBER: Jason Claeys, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1223, Silver Spring, MD 20993–0002, 240–402–8589, *jason.claeys@fda.hhs.gov,* with the subject line ''MIDD Pilot Meetings Program for CBER.''

SUPPLEMENTARY INFORMATION:

I. Background

Under FDARA FDA agreed, in accordance with the ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022: I. Ensuring the Effectiveness of the Human Drug Review Program, Part J. Enhancing Regulatory Decision Tools to Support Drug Development and Review'' to provide information on how a sponsor can apply to participate in a pilot meetings program with FDA to discuss MIDD approaches (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf*).

FDA is announcing this pilot meetings program to satisfy the above-mentioned commitment and to facilitate MIDD approaches. This excludes statistical designs involving complex adaptations, Bayesian methods, or other features requiring computer simulations to determine the operating characteristics of a confirmatory clinical trial. MIDD approaches use a variety of quantitative methods to help balance the risks and benefits of drug products in development. When successfully applied, MIDD approaches can improve clinical trial efficiency, increase the probability of regulatory success, and optimize drug dosing/therapeutic individualization in the absence of dedicated trials.

The goal of the early meeting discussions granted under this pilot program is to provide advice on how specific, proposed MIDD approaches can be used in a specific drug development program. FDA has committed to accepting two to four meeting requests quarterly each fiscal year. The meetings granted will include an initial and followup meeting on the same drug development issues within the span of approximately 120 days.

The listed eligibility factors and procedures outlined in this **Federal Register** notice reflect the current thinking at the time of publication. Processes may be revised and will be communicated as this pilot program evolves. The most current pilot program eligibility factors and procedures may be found on the MIDD Pilot Program website: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm600311.htm.*

II. Eligibility and Selection for Participation in the MIDD Pilot Program

The requester should be a drug/biologics development company (interested consortia or software/device developer should come in partnership with a drug development company) and have an investigational new drug application (IND) or pre-IND (PIND) number for the relevant program. Recognizing that FDA will learn both from the number and types of submissions received for consideration into the pilot program, FDA welcomes submissions related to any relevant MIDD topics. However, given that the Agency expects to grant two to four meeting requests per quarter as part of the pilot program, the Agency will initially prioritize selecting requests that focus on:

- Dose selection or estimation (*e.g.,* for dose/dosing regimen selection or refinement).
- Clinical trial simulation (*e.g.,* based on drug-trial-disease models to inform the duration of a trial, select appropriate response measures, predict outcomes).
- Predictive or mechanistic safety evaluation (*e.g.,* use of systems pharmacology/mechanistic models for predicting safety or identifying critical biomarkers of interest).

III. Procedures and Submission Information

A. General Information

The MIDD pilot program will be jointly administered by CDER's Office of Clinical Pharmacology, in the Office of Translational Sciences, which is the point of contact for all communications for CDER products, and CBER's Office of Biostatistics and Epidemiology, which is the point of contact for all communications for CBER products.

B. How To Submit a Meeting Request and Meeting Package

Meeting requests should be submitted electronically to the relevant application (*i.e.,* PIND, IND) with ''MIDD Pilot Program Meeting Request for CDER'' (CDER applications) or ''MIDD Pilot Program Meeting Request for CBER'' (CBER applications) in the subject line. Information about providing regulatory submissions in electronic format is available at: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/%20ElectronicSubmissions/ucm153574.htm.*

C. Content and Format of the Meeting Request

Include the following information in the meeting request (no more than three to four pages):

1. Product name.
2. Application number.
3. Chemical name and structure.
4. Proposed indication(s) or context of product development.
5. Brief statement of the purpose and objectives of the meeting. The statement should include a brief background of the MIDD issues underlying the agenda.
6. MIDD approach(es) considered for the product under development and how MIDD can assess uncertainties about issues (*e.g.,* dosing, duration, patient selection) in a way that can inform regulatory decision-making.
7. List of issues for discussion with the Agency about the specific MIDD proposed approach for the applicable drug development program.

D. Content and Format of the Meeting Information Package

Sponsors or applicants whose meeting requests are granted as part of the pilot program should submit a meeting information package electronically with ''MIDD Pilot Program Meeting Package for CDER'' (CDER applications) or ''MIDD Pilot Program Meeting Package for CBER'' (CBER applications) in the subject line no later than 30 days before each (initial and followup) meeting. This meeting package should include the following information:

1. Product name.

2. Application number.

3. Chemical name and structure.

4. Proposed indication(s) or context of product development.

5. Background section that includes a brief history of the development program and the events leading up to the meeting, and the status of product development.

6. Proposed agenda, including estimated times needed for discussion of each agenda item.

7. List of questions for discussion with a brief summary for each question to explain the need or context for the question.

8. Drug development issue (*e.g.,* dosing, clinical trial design, safety prediction), including the proposed MIDD approach to the solution, information to support discussion (*e.g.,* a description of the data used for developing the models, model development, simulation plan, results), and how the Agency can help guide any next steps relative to the regulatory decision making process, which should be summarized and clearly articulated with any supporting data imperative to the discussion.

E. Meeting Summaries

A meeting summary will be sent to the requester within 60 days of each meeting.

IV. Paperwork Reduction Act of 1995

This notice refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information resulting from formal meetings between sponsors or applicants and FDA has been approved under OMB control number 0910–0429. The collection of information in 21 CFR part 312 (INDs) has been approved under OMB control number 0910–0014.

Dated: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–08010 Filed 4–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6931]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donation Testing, Donor Notification, and ''Lookback''

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 17, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0116. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donation Testing, Donor Notification, and ''Lookback''

OMB Control Number 0910–0116—Extension

All blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)). Section 351(a) requires that manufacturers of biological products, which include blood and blood components intended for further manufacturing into products, have a license, issued upon a demonstration that the product is safe, pure, and potent and that the manufacturing establishment meets all applicable standards, including those prescribed in the FDA regulations designed to ensure the continued safety, purity, and potency of the product. In addition, under section 361 of the PHS Act (42 U.S.C. 264), by delegation from the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

Section 351(j) of the PHS Act states that the Federal Food, Drug, and Cosmetic Act (FD&C Act) also applies to biological products. Blood and blood components for transfusion or for further manufacturing into products are drugs, as that term is defined in section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)). Because blood and blood components are drugs under the FD&C Act, blood and plasma establishments must comply with the provisions and related regulatory scheme of the FD&C Act. For example, under section 501 of the FD&C Act (21 U.S.C. 351), drugs are deemed ''adulterated'' if the methods used in their manufacturing, processing, packing, or holding do not conform to current good manufacturing practice (CGMP) and related regulations.

The CGMP regulations (part 606) (21 CFR part 606) and related regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components. The public health objective in testing human blood donations for evidence of relevant transfusion-transmitted infections and in notifying donors is to prevent the transmission of relevant transfusion-transmitted infections. For example, the ''lookback'' requirements are intended to help ensure the continued safety of the blood supply by providing necessary information to consignees of blood and blood components and appropriate notification of recipients of blood components that are at increased risk for transmitting human immunodeficiency virus (HIV) or hepatitis C virus (HCV) infection.

The information collection requirements in the CGMP, donation testing, donor notification, and ''lookback'' regulations provide FDA

with the necessary information to perform its duty to ensure the safety, purity, and potency of blood and blood components. These requirements establish accountability and traceability in the processing and handling of blood and blood components and enable FDA to perform meaningful inspections.

The recordkeeping requirements serve preventive and remedial purposes. The third-party disclosure requirements identify various blood and blood components and important properties of the product, demonstrate that the CGMP requirements have been met, and facilitate the tracing of a product back to its original source. The reporting requirements inform FDA of certain information that may require immediate corrective action.

Under the reporting requirements, § 606.170(b) (21 CFR 606.170(b)), in brief, requires that facilities notify FDA's Center for Biologics Evaluation and Research (CBER), as soon as possible after a complication of blood collection or transfusion is confirmed to be fatal. The collecting facility is required to report donor fatalities, and the compatibility testing facility is to report recipient fatalities. The regulation also requires the reporting facility to submit a written report of the investigation within 7 days after the fatality. In fiscal year 2016, FDA received 81 fatality reports.

Section 610.40(g)(2) (21 CFR 610.40(g)(2)) requires an establishment to obtain written approval from FDA to ship human blood or blood components for further manufacturing use prior to completion of testing for evidence of infection due to relevant transfusion-transmitted infections.

Section 610.41(b) (21 CFR 610.41(b)) allows for a previously deferred donor to subsequently be found to be an eligible donor of blood and blood components by a requalification method or process found acceptable for such purposes by FDA.

Section 610.40(h)(2)(ii)(A), in brief, requires an establishment to obtain written approval from FDA to use or ship human blood or blood components found to be reactive by a screening test for evidence of infection due to a relevant transfusion-transmitted infection(s) or collected from a donor deferred under § 610.41(a).

In addition, § 630.35(b) (21 CFR 630.35(b)) allows for a previously deferred donor, deferred for reasons other than § 610.41(a), to become requalified for donation by a method or process found acceptable for such purpose by FDA.

Under the third-party disclosure requirements, § 606.145(c) (21 CFR 606.145(c)) requires transfusion services to notify certain blood collection establishments concerning bacterial contamination of platelets and other additional information. In table 3, FDA estimates that for the approximately 4,961 transfusion services, there would be 1,400 total notifications per year to blood collection establishments (700 notifications that platelets are bacterially contaminated and 700 notifications per year concerning the identity or non-identity of the species of the contaminating organism).

Section 610.40(c)(1)(ii), in brief, requires that each donation dedicated to a single identified recipient be labeled as required under § 606.121 (21 CFR 606.121) and with a label containing the name and identifying information of the recipient. The information collection requirements under § 606.121 are part of usual and customary business practice.

Section 610.40(h)(2)(ii)(C) and (D), in brief, require an establishment to label certain reactive human blood and blood components with the appropriate screening test results for evidence of infection due to the identified relevant transfusion-transmitted infection(s), and, if they are intended for further manufacturing use into products, to include a statement on the label indicating the exempted use specifically approved by FDA. Also, § 610.40(h)(2)(vi) requires each donation of human blood or blood components, excluding Source Plasma, that tests reactive by a screening test for syphilis and is determined to be a biological false positive to be labeled with both test results.

Section 610.42(a) (21 CFR 610.42(a)) requires a warning statement ''indicating that the product was manufactured from a donation found to be reactive by a screening test for evidence of infection due to the identified relevant transfusion-transmitted infection(s)'' in the labeling for medical devices containing human blood or a blood component found to be reactive by a screening test for evidence of infection due to a relevant transfusion-transmitted infection(s) or syphilis.

In brief, §§ 610.46 and 610.47 (21 CFR 610.46 and 610.47) require blood collecting establishments to establish, maintain, and follow an appropriate system for performing HIV and HCV ''lookback'' when: (1) A donor tests reactive for evidence of HIV or HCV infection or (2) the collecting establishment becomes aware of other reliable test results or information indicating evidence of HIV or HCV infection (see §§ 610.46(a)(1) and 610.47(a)(1)). The requirement for ''an appropriate system'' requires the collecting establishment to design standard operating procedures (SOPs) to identify and quarantine all blood and blood components previously collected from a donor who later tests reactive for evidence of HIV or HCV infection, or when the collecting establishment is made aware of other reliable test results or information indicating evidence of HIV or HCV infection. Within 3 calendar days of the donor testing reactive by an HIV or HCV screening test or the collecting establishment becoming aware of other reliable test results or information, the collecting establishment must, among other things, notify consignees to quarantine all identified previously collected in-date blood and blood components (§§ 610.46(a)(1)(ii)(B) and 610.47(a)(1)(ii)(B)) and, within 45 days, notify the consignees of supplemental test results, or the results of a reactive screening test if there is no available supplemental test that is approved for such use by FDA (§§ 610.46(a)(3) and 610.47(a)(3)).

Consignees also must establish, maintain, and follow an appropriate system for performing HIV and HCV ''lookback'' when notified by the collecting establishment that they have received blood and blood components previously collected from donors who later tested reactive for evidence of HIV or HCV infection, or when the collecting establishment is made aware of other reliable test results or information indicating evidence of HIV or HCV infection in a donor (§§ 610.46(b) and 610.47(b)). This provision for a system requires the consignee to establish SOPs for, among other things, notifying transfusion recipients of blood and blood components, or the recipient's physician of record or legal representative, when such action is indicated by the results of the supplemental (additional, more specific) tests or a reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an investigational new drug application (IND) or an investigational device exemption (IDE), is exempted for such use by FDA. The consignee must make reasonable attempts to perform the notification within 12 weeks of receipt of the supplemental test result or receipt of a reactive screening test result when there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA (§§ 610.46(b)(3) and 610.47(b)(3)). The burden for the recordkeeping requirements under §§ 610.46(a) and (b) and 610.47(a) and

(b) are included under § 606.100 (21 CFR 606.100).

Section 630.40(a) (21 CFR 630.40(a)) requires an establishment to make reasonable attempts to notify any donor who has been deferred as required by § 610.41(a), or who has been determined not to be eligible as a donor. Section 630.40(d)(1) requires an establishment to provide certain information to the referring physician of an autologous donor who is deferred based on the results of tests as described in § 610.41.

Under the recordkeeping requirements, § 606.100(b), in brief, requires that written SOPs be maintained for all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components used for transfusion and further manufacturing purposes. Section 606.100(c) requires the review of all records pertinent to the lot or unit of blood prior to release or distribution. Any unexplained discrepancy or the failure of a lot or unit of final product to meet any of its specifications must be thoroughly investigated, and the investigation, including conclusions and followup, must be recorded.

In brief, § 606.110(a) (21 CFR 606.110(a)) provides that the use of plateletpheresis and leukapheresis procedures to obtain a product for a specific recipient may be at variance with the additional standards for that specific product if, among other things, the physician determines and documents that the donor's health permits plateletpheresis or leukapheresis. Section 606.110(b) requires establishments to request prior approval from CBER for plasmapheresis of donors who do not meet donor requirements. The information collection requirements for § 606.110(b) are approved under OMB control number 0910–0338 and, therefore, are not reflected in the tables of this document.

Section 606.151(e) (21 CFR 606.151(e)) requires that SOPs for compatibility testing include procedures to expedite transfusion in life-threatening emergencies; records of all such incidents must be maintained, including complete documentation justifying the emergency action, which must be signed by a physician.

Section 606.171 (21 CFR 606.171) requires establishments to establish and maintain procedures related to product deviations. The burden for the recordkeeping requirements under § 606.171 are included under § 606.100.

So that each significant step in the collection, processing, compatibility testing, storage, and distribution of each unit of blood and blood components can be clearly traced, § 606.160 (21 CFR 606.160) requires that legible and indelible contemporaneous records of each such step be made and maintained for no less than 10 years. Section 606.160(b)(1)(viii) requires records of the quarantine, notification, testing, and disposition performed under the HIV and HCV ''lookback'' provisions. Furthermore, § 606.160(b)(1)(x) requires a blood collection establishment to maintain records of notification of donors deferred or determined not to be eligible for donation, including appropriate followup. Section 606.160(b)(1)(xi) requires an establishment to maintain records of notification of the referring physician of a deferred autologous donor, including appropriate followup.

Section 606.165 (21 CFR 606.165), in brief, requires that distribution and receipt records be maintained to facilitate recalls, if necessary.

Section 606.170(a) requires records to be maintained of any reports of complaints of adverse reactions arising as a result of blood collection or transfusion. Each such report must be thoroughly investigated, and a written report, including conclusions and followup, must be prepared and maintained. Section 606.170(a) also requires that when an investigation determines that the product caused the transfusion reaction, copies of all such written reports must be forwarded to and maintained by the manufacturer or collecting facility.

Section 610.40(g)(1) requires an establishment to appropriately document a medical emergency for the release of human blood or blood components prior to completion of required testing.

Under § 630.15(a)(1)(ii)(B) (21 CFR 630.15(a)(1)(ii)(B)), FDA requires that for a dedicated donation based on the intended recipient's documented exceptional medical need, the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.

Under § 630.20(c) (21 CFR 630.20(c)), a collection establishment may collect blood and blood components from a donor who is determined to be not eligible to donate under any provision of § 630.10(e) and (f) or § 630.15(a), if the donation is restricted for use solely by a specific transfusion recipient based on documented exceptional medical need and the responsible physician determines and documents that the donor's health permits the collection procedure, and that the donation presents no undue medical risk to the transfusion recipient.

In addition to the CGMP regulations in part 606, the regulations in 21 CFR part 630 that include requirements for blood and blood components intended for transfusion or further manufacturing use and in 21 CFR part 640 that require additional standards for certain blood and blood products are as follows: 21 CFR 630.5(b)(1)(i) and(d); 630.10(c)(1) and (2); 630.10(f)(2) and (4); 630.10(g)(2)(i); 630.15(a)(1)(ii)(A) and (B); 630.15(b)(2), (b)(7)(i) and (iii); 630.20(a) and (b); 640.21(e)(4); 640.25(b)(4) and (c)(1); 640.31(b); 640.33(b); 640.51(b); 640.53(b) and (c); 640.56(b) and (d); 640.65(b)(2)(i); 640.66; 640.71(b)(1); 640.72; 640.73; and 640.76(a) and (b). The information collection requirements and estimated burdens for these regulations are included in the part 606 burden estimates, as described in tables 1 and 2.

Respondents to this collection of information are licensed and unlicensed blood establishments that collect blood and blood components, including Source Plasma and Source Leukocytes, inspected by FDA, and transfusion services inspected by Centers for Medicare and Medicaid Services (CMS). Based on information received from CBER's database systems, there are approximately 569 licensed Source Plasma establishments and approximately 1,054 licensed blood collection establishments, for an estimated total of 1,623 (569 + 1,054) licensed blood collection establishments. Also, there are an estimated total of 680 unlicensed, registered blood collection establishments for an approximate total of 2,303 collection establishments (569 + 1,054 + 680 = 2,303 establishments). Of these establishments, approximately 901 perform plateletpheresis and leukopheresis. These establishments annually collect approximately 53.3 million units of Whole Blood and blood components, including Source Plasma and Source Leukocytes, and are required to follow FDA ''lookback'' procedures. In addition, there are another estimated 4,961 establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (formerly referred to as facilities approved for Medicare reimbursement) that transfuse blood and blood components.

The following reporting, recordkeeping, and disclosure estimates are based on information provided by industry, CMS, and FDA experience. Based on information from industry, we estimate that there are approximately

38.3 million donations of Source Plasma from approximately 2 million donors and approximately 15 million donations of Whole Blood and apheresis Red Blood Cells including approximately 34,500 (approximately 0.23 percent of 15 million) autologous donations, from approximately 10.9 million donors. Assuming each autologous donor makes an average of 1.1 donations, FDA estimates that there are approximately 31,364 autologous donors (34,500 autologous/1.1 average donations).

FDA estimates that approximately 0.19 percent (21,000/10,794,000) of the 72,000 donations that are donated specifically for the use of an identified recipient would be tested under the dedicated donors' testing provisions in § 610.40(c)(1)(ii).

Under § 610.40(g)(2) and (h)(2)(ii)(A), Source Leukocytes, a licensed product that is used in the manufacture of interferon, which requires rapid preparation from blood, is currently shipped prior to completion of testing for evidence of relevant transfusion-transmitted infections. Shipments of Source Leukocytes are approved under a biologics license application and each shipment does not have to be reported to the Agency. Based on information from CBER's database system, FDA receives less than one application per year from manufacturers of Source Leukocytes. However, for calculation purposes, we are estimating one application annually.

According to CBER's database system, there are approximately 15 licensed manufacturers that ship known reactive human blood or blood components under § 610.40(h)(2)(ii)(C) and (D). FDA estimates that each manufacturer would ship an estimated 1 unit of human blood or blood components per month (12 per year) that would require two labels; one as reactive for the appropriate screening test under § 610.40(h)(2)(ii)(C), and the other stating the exempted use specifically approved by FDA under § 610.40(h)(2)(ii)(D).

Based on information received from industry, we estimate that approximately 7,544 donations will test reactive by a screening test for syphilis and be determined to be biological false positives by additional testing annually. These units would be labeled according to § 610.40(h)(2)(vi).

Human blood or a blood component with a reactive screening test, as a component of a medical device, is an integral part of the medical device, *e.g.,* a positive control for an in vitro diagnostic testing kit. It is usual and customary business practice for manufacturers to include on the container label a warning statement indicating that the product was manufactured from a donation found to be reactive for the identified relevant transfusion-transmitted infection(s). In addition, on the rare occasion when a human blood or blood component with a reactive screening test is the only component available for a medical device that does not require a reactive component, then a warning statement must be affixed to the medical device. To account for this rare occasion under § 610.42(a), we estimate that the warning statement would be necessary no more than once a year.

FDA estimates that approximately 3,021 repeat donors will test reactive on a screening test for HIV. We also estimate that an average of three components was made from each donation. Under § 610.46(a)(1)(ii)(B) and (a)(3), this estimate results in 9,063 (3,021 × 3) notifications of the HIV screening test results to consignees by collecting establishments for the purpose of quarantining affected blood and blood components, and another 9,063 (3,021 × 3) notifications to consignees of subsequent test results.

We estimate that approximately 4,961 consignees will be required under § 610.46(b)(3) to notify transfusion recipients, their legal representatives, or physicians of record an average of 0.35 times per year resulting in a total number of 1,755 (585 confirmed positive repeat donors × 3) notifications. Also under § 610.46(b)(3), we estimate and include the time to gather test results and records for each recipient and to accommodate multiple attempts to contact the recipient.

Furthermore, we estimate that approximately 6,799 repeat donors per year would test reactive for antibody to HCV. Under § 610.47(a)(1)(ii)(B) and (a)(3), collecting establishments would notify the consignee two times for each of the 20,397 (6,799 × 3 components) components prepared from these donations, once for quarantine purposes and again with additional HCV test results for a total of 40,794 (20,397 × 2) notifications as an annual ongoing burden. Under § 610.47(b)(3), we estimate that approximately 4,961 consignees would notify approximately 2,050 recipients or their physicians of record annually.

Based on industry estimates, approximately 14.3 percent of approximately 9 million potential donors (1,287,000 donors) who come to donate annually are determined not to be eligible for donation prior to collection because of failure to satisfy eligibility criteria. It is the usual and customary business practice of approximately 1,734 (1,054 + 680) blood collecting establishments to notify onsite and to explain why the donor is determined not to be suitable for donating. Based on such available information, we estimate that two-thirds (1,156) of the 1,734 blood collecting establishments provided onsite additional information and counseling to a donor determined not to be eligible for donation as usual and customary business practice. Consequently, we estimate that only approximately one-third, or 578 of the 1,734 blood collecting establishments would need to provide, under § 630.40(a), additional information and onsite counseling to the estimated 429,000 (one-third of approximately 1,287,000) ineligible donors.

It is estimated that another 4.5 percent of 10 million potential donors (450,000 donors) are deferred annually based on test results. We estimate that approximately 95 percent of the establishments that collect 99 percent of the blood and blood components notify donors who have reactive test results for HIV, hepatitis B virus, HCV, human T-lymphotropic virus, and syphilis as usual and customary business practice. Consequently, 5 percent of the 1,623 licensed establishments (81) collecting 1 percent (4,050) of the deferred donors (405,000) would notify donors under § 630.40(a).

As part of usual and customary business practice, collecting establishments notify an autologous donor's referring physician of reactive test results obtained during the donation process required under § 630.40(d)(1). However, we estimate that approximately 5 percent of the 1,054 blood collection establishments (53) may not notify the referring physicians of the estimated 2 percent of 31,364 autologous donors with the initial reactive test results (627) as their usual and customary business practice.

The recordkeeping chart reflects the estimate that approximately 95 percent of the recordkeepers, which collect 99 percent of the blood supply, have developed SOPs as part of their customary and usual business practice. Establishments may minimize burdens associated with CGMP and related regulations by using model standards developed by industries' accreditation organizations. These accreditation organizations represent almost all registered blood establishments.

Under § 606.160(b)(1)(x), we estimate the total annual records based on the approximately 1,287,000 donors determined not to be eligible to donate and each of the estimated 1,692,000 (1,287,000 + 405,000) donors deferred based on reactive test results for

evidence of infection because of relevant transfusion-transmitted infections. Under § 606.160(b)(1)(xi), only the 1,734 registered blood establishments collect autologous donations and, therefore, are required to notify referring physicians. We estimate that 4.5 percent of the 31,364 autologous donors (1,411) will be deferred under § 610.41, which in turn will lead to the notification of their referring physicians.

Under § 610.41(b), FDA estimates that there would be 25 submissions for requalification of donors. In addition, FDA estimates that there would be only three notifications for requalification of donors under § 630.35(b). FDA also estimates the average time for each submission.

FDA permits the shipment of untested or incompletely tested human blood or blood components in rare medical emergencies and when appropriately documented (§ 610.40(g)(1)). We estimate the recordkeeping under § 610.40(g)(1) to be minimal with one or fewer occurrences per year. The reporting of test results to the consignee in § 610.40(g) is part of the usual and customary business practice of blood establishments.

In the **Federal Register** of January 23, 2018 (83 FR 3165), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

The average burden per response (hours) and average burden per recordkeeping (hours) are based on estimates received from industry or FDA experience with similar reporting or recordkeeping requirements.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
606.170(b) [2]	81	1	81	20	1,620
610.40(g)(2)	1	1	1	1	1
610.41(b)	1,623	0.015	25	7	175
610.40(h)(2)(ii)(A)	1	1	1	1	1
630.35(b)	1,623	0.002	3	7	21
Total					1,818

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The reporting requirement in § 640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for § 606.170(b).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
606.100(b) [2]	[5] 363	1	363	24	8,712
606.100(c)	[5] 363	10	3,630	1	3,630
606.110(a) [3]	[6] 45	1	45	0.5 (30 min)	23
606.151(e)	[5] 363	12	4,356	0.08 (5 min.)	348
606.160 [4]	[5] 363	1,055.096	383,000	0.75 (45 min.)	287,250
606.160(b)(1)(viii) HIV consignee notification	1,734	10.4533	18,126	0.17 (10 min.)	3,081
				0.17 (10 min.)	
	4,961	3.6537	18,126		3,081
606.160(b)(1)(viii) HCV consignee notification	1,734	23.5259	40,794	0.17 (10 min.)	6,935
				0.17 (10 min)	
	4,961	8.2229	40,794		6,935
HIV recipient notification	4,961	0.3538	1,755	0.17 (10 min.)	298
HCV recipient notification	4,961	0.4132	2,050	0.17 (10 min.)	349
606.160(b)(1)(x)	2,303	734.6939	1,692,000	0.05 (3 min.)	84,600
606.160(b)(1)(xi)	1,734	0.8137	1,411	0.05 (3 min.)	71
606.165	[5] 363	1,055.096	383,000	0.08 (5 min.)	30,640
606.170(a)	[5] 363	12	4,356	1	4,356
610.40(g)(1)	2,303	1	2,303	0.5 (30 min.)	1,152
630.15(a)(1)(ii)(B)	1,734	1	1,734	1	1,734
630.20(c)	1,734	1	1,734	1	1,734
Total					444,930

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The recordkeeping requirements in §§ 606.171, 610.46(a) and (b), 610.47(a) and (b), 630.5(d), 630.10(c)(1) and (2), and 640.66, which address the maintenance of SOPs, are included in the estimate for § 606.100(b).
[3] The recordkeeping requirements in § 640.27(b), which address the maintenance of donor health records for the plateletpheresis, are included in the estimate for § 606.110(a).
[4] The recordkeeping requirements in §§ 606.110(a)(2); 630.5(b)(1)(i); 630.109(f)(2) and (4); 630.10(g)(2)(i); 630.15(a)(1)(ii)(A) and (B); 630.15(b)(2), (b)(7)(i) and (iii); 630.20(a) and (b); 640.21(e)(4); 640.25(b)(4) and (c)(1); 640.31(b); 640.33(b); 640.51(b); 640.53(b) and (c); 640.56(b) and (d); 630.15(b)(2); 640.65(b)(2)(i); 640.71(b)(1); 640.72; 640.73; and 640.76(a) and (b), which address the maintenance of various records are included in the estimate for § 606.160.
[5] Five percent of establishments that fall under CLIA that transfuse blood and components and FDA-registered blood establishments ($0.05 \times 4{,}961 + 2{,}303 = 363$).
[6] Five percent of plateletpheresis and leukopheresis establishments ($0.05 \times 901 = 45$).

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
606.145(c)	4,961	0.2822	1,400	0.02	28
606.170(a)	[2] 363	12	4,356	0.5 (30 min.)	2,178
610.40(c)(1)(ii)	2,303	0.0595	137	0.08 (5 min.)	11
610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)	15	12	180	0.20 (12 min.)	36
610.40(h)(2)(vi)	2,303	3.28	7,554	0.08 (5 min.)	604
610.42(a)	1	1	1	1	1
610.46(a)(1)(ii)(B)	1,734	5.2266	9,063	0.17 (10 min.)	1,541
610.46(a)(3)	1,734	5.2266	9,063	0.17 (10 min.)	1,541
610.46(b)(3)	4,961	0.3538	1,755	1	1,755
610.47(a)(1)(ii)(B)	1,734	11.7630	20,397	0.17 (10 min.)	3,467
610.47(a)(3)	1,734	11.7630	20,397	0.17 (10 min.)	3,467
610.47(b)(3)	4,961	0.4132	2,050	1	2,050
630.40(a) [3]	578	742.214	429,000	0.08 (5 min.)	34,320
630.40(a) [4]	81	50	4,050	1.5	6,075
630.40(d)(1)	53	11.83	627	1	627
Total					57,701

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Five percent of establishments that fall under CLIA that transfuse blood and components and FDA-registered blood establishments (0.05 × 4,961 + 2,303 = 363).
[3] Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.
[4] Notification of donors deferred based on reactive test results for evidence of infection due to relevant transfusion-transmitted infections.

The burden for this information collection has changed since the last OMB approval. Because of a slight decrease in the number of blood establishments during the last 3 years, FDA has decreased our recordkeeping and third-party disclosure burden estimates.

Dated: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) will hold a public meeting.

DATES: Thursday, May 3, 2018, from 8:30 a.m. to 5:00 p.m. and Friday, May 4, 2018, from 8:30 a.m. to 2:00 p.m. ET.

ADDRESSES: The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857, Room 5E29. The conference call-in number: 1–800–857–9729 and Passcode: 1318150. The webinar link is *https://hrsa.connectsolutions.com/actpcmd.*

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding the ACTPCMD should contact Dr. Kennita R. Carter, Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, in one of three ways: (1) Send a request to the following address: Dr. Kennita R. Carter, DFO, Division of Medicine and Dentistry, HRSA, 5600 Fishers Lane, Room 15N–116, Rockville, MD 20857; (2) call 301–945–3505; or (3) send an email to *KCarter@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACTPCMD provides advice and recommendations to the Secretary of the Department of Health and Human Services on policy, program development, and other matters of significance concerning the activities under section 747 of Title VII of the Public Health Service Act (PHSA). ACTPCMD prepares an annual report describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary and ranking members of the Senate Committee on Health, Education, Labor and Pensions, and the House of Representatives Committee on Energy and Commerce. The Committee also develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under Title VII, Part C, of the PHSA, and recommends appropriation levels for programs under this Part.

During the May 3–4, 2018, meeting, ACTPCMD will review the impact of the Title VII, Section 747 and oral health training programs, and make recommendations on funding and appropriation levels. In addition, the Committee will identify its strategic priorities for the coming year, and discuss issues related to pending Committee reports on the integration of behavioral health into primary care and oral health training, and clinical trainee and faculty well-being and resilience. Information about ACTPCMD and the agenda for this meeting is located on the ACTPCMD website at *https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html.* Please note that agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the ACTPCMD should be sent to Dr. Carter, DFO, using the contact information above at least three business days prior to the meeting.

The building at 5600 Fishers Lane, Rockville, MD 20857, requires a security screening on entry. To facilitate access to the building, please contact Dr. Carter at the contact information listed above. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Dr. Carter at the address and phone number listed above at least 10 days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–07910 Filed 4–16–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Date and Times: Tuesday, May 15, 2018: 9:00 a.m.–5:00 p.m. (EDT), Wednesday, May 16, 2018: 8:30 a.m.–2:45 p.m. (EDT).

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW, Rm. 705A, Washington, DC 20201.

Status: Open.

Purpose: At the May 15–16, 2018 meeting, the Committee will hear presentations, hold discussions on several health data policy topics and work on activities outlined in the NCVHS 2018 workplan. Anticipated action items during this meeting include a letter to the Secretary and a summary report of the hearing held September 2017 on the topic of the national vital records and vital statistics systems. In addition, a letter to the Secretary regarding the Committee's recommendations resulting from the March Standards Subcommittee Hearing on NCPDP Updates will be considered for approval. The Office of the National Coordinator (ONC) will give an update and the Committee will discuss its collaboration with ONC and its advisory committee HITAC. Subcommittee activities for discussion include the CIO Forum to be held in May and the Predictability Roadmap as part of the Standards Subcommittee's project to identify possible approaches to improve predictability and improvements in the adoption and processes related to updating standards and operating rules for electronic administrative transactions (*e.g.,* claims, eligibility, electronic funds transfer). The agenda and plans for the July meeting examining health terminology & vocabulary development, maintenance, and dissemination processes will be discussed together with a draft environmental scan report. The Committee will continue development of its Health Information Privacy & Security Beyond HIPAA project focusing on clinical registries as a use case. The Committee also will discuss any recent developments resulting from the initial wave of the Medicare Card Project roll out.

The times and topics are subject to change. Please refer to the posted agenda for any updates.

Contact Persons for More Information: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS website: *www.ncvhs.hhs.gov,* where further information including an agenda and instructions to access the audio broadcast of the meetings will also be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488–3210 as soon as possible.

Dated: April 10, 2018.

Laina Bush,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2018–07928 Filed 4–16–18; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Standards Subcommittee Meeting.

Date and Times: Thursday, May 17, 2018: 9:00 a.m.–4:30 p.m. (EDT).

Place: Bureau of Labor Statistics, Janet Norwood Conference and Training Center, Postal Square Building, 2 Massachusetts Ave NE, Room G440, Washington, DC 20212 (Entrance on First Street across from Union Station).

Status: Open. There will be a public comment period during the final 15 minutes of the subcommittee meeting.

Purpose: Health Insurance Portability and Accountability Act (HIPAA) legislation from 1996, as amended,[1] directed the Secretary of HHS to publish regulations adopting administrative standards, code sets and identifiers to support the exchange of electronic health information between covered entities. The standards are for retail pharmacy and medical transactions.

NCVHS is working on the development of a standards update and adoption roadmap (the predictability roadmap), in collaboration with industry stakeholders and the Standards Development Organizations (SDOs). The purpose of this roadmap is to improve the predictability of the update and adoption process of the standards and operating rules. It is the intent of the collaboration effort to identify the barriers to updating and adopting standards and make constructive, actionable recommendations for all parties, so that covered entities can more effectively conduct their business, operational and technical strategic planning.

NCVHS held a visioning exercise with the Standards Development Organizations (SDOs) in August 2017, and developed a set of draft action steps and recommendations. The next step towards finalizing recommendations for the Secretary, is to convene a group of Chief Information Officers (CIOs) who work with the standards and operating rules as end users, with health care leaders from various fields of health care technology. The CIOs and health care innovators will exchange information based on their experience and expertise. The CIOs will discuss their changing business and technology needs specifically as these pertain to the standards that have been adopted under HIPAA such as claims, eligibility, referrals and authorizations. Some individuals will share their experience using the standards day to day, and to increase efficiencies in their organizations. Other participants will share their experience implementing or seeing innovative technology being used for the exchange of electronic health care information.

[1] Along with Section 1104(c) of the Patient Protection and Affordable Care Act (ACA) of 2010.

During the second part of the forum, the group will engage in an open discussion about the roadmap themes and develop additional action items and recommendations for the Secretary. The roadmap themes and their problem statements are listed below:

1. Standards Development and update process. Frequency of updates to standards and operating rules is not aligned with industry business and technical changes and does not enable covered entities, trading partners, or business associates to take advantage of developments in technology.

2. Governance, or oversight of the standards review process (currently the Designated Standards Maintenance Organization or DSMO process established through regulation). Current coordinating body (*i.e.,* the DSMO) is charged with oversight of standards revision priorities but may be operating with too narrow a charter or lacking the authority and resources to be effective.

3. Federal regulatory process to adopt new versions of standards. The Federal process for adoption of standards and operating rules is lengthy, of unpredictable duration and contains numerous checks and balances that duplicate similar processes within the standards development organizations. The lack of predictability and timeliness jeopardizes the smooth adoption and uptake of standards and operating rules once they are developed and published by the SDO.

4. Data harmonization. The lack of data cohesion due to inconsistencies in data dictionaries and data elements across SDOs jeopardizes interoperability.

5. Inclusion of non-covered entities under HIPAA. Covered entities include providers, health plans and health care clearinghouses. Vendors and other business associates are not covered entities but often play a role in the exchange and/or processing of the adopted standards. The Federal government is limited in its authority over non-covered entities. This impacts the use of standards in a variety of ways, from costs to actual utilization.

The times and topics are subject to change. Please refer to the posted agenda for any updates.

Contact Persons for More Information: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458–4715. Information pertaining to meeting content may be obtained from Lorraine Doo, MSW, MPH, Centers for Medicare & Medicaid Services, Office of Information Technology, Division of National Standards, 7500 Security Boulevard, Baltimore, Maryland, 21244, telephone (443) 615–1309. Summaries of meetings and a roster of Committee members are available on the NCVHS website: *www.ncvhs.hhs.gov,* where further information including an agenda and instructions to access the live audio broadcast of the meetings will also be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488–3210 as soon as possible.

Dated: April 10, 2018.

Laina Bush,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2018–07926 Filed 4–16–18; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Tribal Self-Governance; Negotiation Cooperative Agreement

Announcement Type: New—Limited Competition

Funding Announcement Number: HHS–2018–IHS–TSGN–0001

Catalog of Federal Domestic Assistance Number: 93.444

Key Dates

Application Deadline Date: June 17, 2018

Review Date: June 25–29, 2018

Earliest Anticipated Start Date: July 15, 2018

Tribal Resolutions Due Date: June 17, 2018

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting applications for Negotiation Cooperative Agreements for the Tribal Self-Governance Program (TSGP). This program is authorized under: Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5383(e). This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.444.

Background

The TSGP is more than an IHS program; it is an expression of the Government-to-Government relationship between the United States (U.S.) and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume Programs, Services, Functions, and Activities (PSFAs), or portions thereof, which gives Tribes the authority to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP affords Tribes the most flexibility to tailor health care PSFAs and is one of three ways that Tribes can choose to obtain health care from the Federal Government for their citizens. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS, (2) contract with the IHS to administer individual programs and services the IHS would otherwise provide (referred to as Title I Self-Determination Contracting, and (3) compact with the IHS to assume control over health care programs the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive and Tribes may choose to combine options based on their individual needs and circumstances.

The TSGP is a tribally driven initiative, and strong Federal-Tribal partnerships are essential to the program's success. The IHS established the OTSG to implement the Tribal Self-Governance authorities under the ISDEAA. The primary OTSG functions are to: (1) Serve as the primary liaison and advocate for Tribes participating in the TSGP, (2) develop, direct, and implement TSGP policies and procedures, (3) provide information and technical assistance to Self-Governance Tribes, and (4) advise the IHS Director on compliance with TSGP policies, regulations, and guidelines. Each IHS Area has an Agency Lead Negotiator (ALN), designated by the IHS Director to act on his or her behalf, who has authority to negotiate Self-Governance Compacts and Funding Agreements (FA). Prospective Tribes interested in participating in the TSGP should contact their respective ALN to begin the Self-Governance planning process. Also, Tribes currently participating in the TSGP, who are interested in expanding existing or adding new PSFAs, should also contact their respective ALN to discuss the best methods for expanding or adding new PSFAs.

Purpose

The purpose of this Negotiation Cooperative Agreement is to provide Tribes with resources to help defray the costs associated with preparing for and engaging in TSGP negotiations. TSGP

negotiations are a dynamic, evolving, and tribally driven process that requires careful planning, preparation and sharing of precise, up-to-date information by both Tribal and Federal parties. Because each Tribal situation is unique, a Tribe's successful transition into the TSGP, or expansion of their current program, requires focused discussions between the Federal and Tribal negotiation teams about the Tribe's specific health care concerns and plans. One of the hallmarks of the TSGP is the collaborative nature of the negotiations process, which is designed to: (1) Enable a Tribe to set its own priorities when assuming responsibility for IHS PSFAs, (2) observe and respect the Government-to-Government relationship between the U.S. and each Tribe, and (3) involve the active participation of both Tribal and IHS representatives, including the OTSG. Negotiations are a method of determining and agreeing upon the terms and provisions of a Tribe's Compact and FA, the implementation documents required for the Tribe to enter into the TSGP. The Compact sets forth the general terms of the Government-to-Government relationship between the Tribe and the Secretary of the U.S. Department of Health and Human Services (HHS). The FA: (1) Describes the length of the agreement (whether it will be annual or multi-year), (2) identifies the PSFAs, or portions thereof, the Tribe will assume, (3) specifies the amount of funding associated with the Tribal assumption, and (4) includes terms required by Federal statute and other terms agreed to by the parties. Both documents are required to participate in the TSGP and they are mutually negotiated agreements that become legally binding and mutually enforceable after both parties sign the documents. Either document can be renegotiated at the request of the Tribe.

The negotiations process has four major stages, including: (1) Planning, (2) pre-negotiations, (3) negotiations, and (4) post-negotiations. Title V of the ISDEAA requires that a Tribe or Tribal organization complete a planning phase to the satisfaction of the Tribe. The planning phase must include legal and budgetary research and internal Tribal Government planning and organizational preparation relating to the administration of health care programs. *See* 25 U.S.C. 5383(d). The planning phase is critical to negotiations and helps Tribes make informed decisions about which PSFAs to assume and what organizational changes or modifications are necessary to support those PSFAs. A thorough planning phase improves timeliness and efficient negotiations and ensures that the Tribe is fully prepared to assume the transfer of IHS PSFAs to the Tribal health program.

During pre-negotiations, the Tribal and Federal negotiation teams review and discuss issues identified during the planning phase. Pre-negotiations provide an opportunity for the Tribe and the IHS to identify and discuss issues directly related to the Tribe's Compact, FA and Tribal shares. They may take the form of a formal meeting or a series of informal meetings or conference calls.

In advance of final negotiations, the Tribe should work with the IHS to secure the following: (1) Program titles and descriptions, (2) financial tables and information, (3) information related to the identification and justification of residuals, and (4) the basis for determining Tribal shares (distribution formula). The Tribe may also wish to discuss financial materials that show estimated funding for next year, and the increases or decreases in funding it may receive in the current year, as well as the basis for those changes.

Having reviewed the draft documents and funding tables, at final negotiations both negotiation teams work together in good faith to determine and agree upon the terms and provisions of the Tribe's Compact and FA. Negotiations are not an allocation process; they provide an opportunity to mutually review and discuss budget and program issues. As issues arise, both negotiations teams work through the issues to reach agreement on the final documents.

There are various entities involved throughout the negotiations process. For example, a Tribal government selects its representative(s) for negotiations and the Tribal negotiations team, which may include a Tribal leader from the governing body, a Tribal health director, technical and program staff, legal counsel, and other consultants. Regardless of the composition of the Tribal team, Tribal representatives must have decision making authority from the Tribal governing body to successfully negotiate and agree to the provisions within the agreements. The Federal negotiations team is led by the ALN and may include area and headquarters staff, including staff from the OTSG, the Office of Finance and Accounting, and the Office of the General Counsel. The ALN is the only member of the Federal negotiations team with delegated authority to negotiate on behalf of the IHS Director. The ALN is the designated official that provides Tribes with Self-Governance information, assists Tribes in planning, organizes meetings between the Tribe and the IHS, and coordinates the Agency's response to Tribal questions during the negotiations process. The ALN role requires detailed knowledge of the IHS, awareness of current policy and practice, and understanding of the rights and authorities available to a Tribe under Title V of the ISDEAA.

In post-negotiations, after the Compact, FA and all negotiations are complete, the documents are signed by the authorizing Tribal official and submitted to the ALN who reviews the final package to ensure each document accurately reflects what was negotiated. Once the ALN completes this review, then the final package is submitted to the OTSG to be prepared for the IHS Director's signature, provided that no outstanding issues delay or prevent signature. After the Compact and FA have been signed by both parties, they become legally binding and enforceable agreements. A signed Compact and FA are necessary for the payment process to begin. The negotiating Tribe then becomes a ''Self-Governance Tribe'' and a participant in the TSGP.

Acquiring a Negotiation Cooperative Agreement is not a prerequisite to enter the TSGP. A Tribe may use other resources to develop and negotiate its Compact and FA. *See* 42 CFR 137.26. Tribes that receive a Negotiation Cooperative Agreement are not obligated to participate in Title V and may choose to delay or decline participation or expansion in the TSGP.

Limited Competition Justification

There is limited competition under this announcement because the authorizing legislation restricts eligibility to Tribes that meet specific criteria identified in Section III. Eligibility Criteria, 1. Eligibility, A. *See* 25 U.S.C. 5383(e); 42 CFR 137.10 and 42 CFR 137.24–26.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2018 is approximately $240,000. Individual award amounts are anticipated to be $48,000. The amount of funding available for awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately five awards will be issued under this program announcement.

Period of Performance

The period of performance is for one year and runs from July 15, 2018, to July 14, 2019.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. However, the IHS is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both the IHS and the grantee. The IHS will be responsible for activities listed under section A and the grantee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for the Cooperative Agreement

A. IHS Programmatic Involvement

(1) Provide descriptions of PSFAs and associated funding at all organizational levels (Service Unit, Area, and Headquarters), including funding formulas and methodologies related to determining Tribal shares.

(2) Meet with Negotiation Cooperative Agreement recipients to provide program information and discuss methods currently used to manage and deliver health care.

(3) Identify and provide statutes, regulations, and policies that provide authority for administering IHS programs.

(4) Provide technical assistance on the IHS budget, Tribal shares, and other topics as needed.

B. Grantee Cooperative Agreement Award Activities

(1) Determine the PSFAs that will be negotiated into the Tribe's Compact and FA. Prepare and discuss each Program, Service Function and Activity in comparison to the current level of services provided so that an informed decision can be made on new or expanded program assumption.

(2) Identify Tribal shares associated with the PSFAs that will be included in the FA.

(3) Develop the terms and conditions that will be set for in both the Compact and FA to submit to the ALN prior to negotiations.

III. Eligibility Information

1. Eligibility

To be eligible for the New Limited Competition Negotiation Cooperative Agreement under this announcement, an applicant must:

(A) Be an ''Indian Tribe'' as defined in 25 U.S.C. 5304(e); a ''Tribal Organization'' as defined in 25 U.S.C. 5304(l); or an ''Inter-Tribal Consortium: as defined at 42 CFR 137.10. However, Alaska Native Villages or Alaska Native Village Corporations are not eligible if they are located within the area served by an Alaska Native regional health entity. See Consolidated Appropriations Act, 2014, Public Law 113–76. By statute, the Native Village of Eyak, Eastern Aleutian Tribes, and the Council for Athabascan Tribal Governments have also been deemed Alaska Native regional health entities and therefore are eligible to apply. Those Alaska Tribes not represented by a Self-Governance Tribal consortium FA within their area may still be considered to participate in the TSGP.

(B) Submit Tribal resolution(s) from the appropriate governing body of each Indian Tribe to be served by the ISDEAA Compact authorizing the submission of the Negotiation Cooperative Agreement. Tribal consortia applying for a TSGP Negotiation Cooperative Agreement shall submit Tribal Council resolutions from each Tribe in the consortium. Tribal resolutions can be attached to the electronic online application.

(C) Demonstrate for three fiscal years, financial stability and financial management capability. The Indian Tribe must provide evidence that, for the three fiscal years prior to requesting participation in the TSGP, the Indian Tribe has had no uncorrected significant and material audit exceptions in the required annual audit of the Indian Tribe's Self-Determination Contracts or Self-Governance FAs with any Federal Agency. *See* 25 U.S.C. 5383; 42 CFR 137.15–23.

For Tribes or Tribal organizations (T/TO) that expended $750,000 or more ($500,000 for fiscal years ending after December 31, 2003) in Federal awards, the OTSG shall retrieve the audits directly from the Federal Audit Clearinghouse.

For T/TO that expended less than $750,000 ($500,000 for fiscal years ending after December 31, 2003) in Federal awards, the T/TO must provide evidence of the program review correspondence from IHS or Bureau of Indian Affairs officials. *See* 42 CFR 137.21–23.

Meeting the eligibility criteria for a Negotiation Cooperative Agreement does not mean that a Tribe/Tribal Organization is eligible for participation in the IHS TSGP under Title V of the ISDEAA. *See* 25 U.S.C. 5383; 42 CFR 137.15–23. For additional information on the eligibility for the IHS TSGP, please visit the ''Eligibility and Funding'' page on the OTSG website located at: *http://www.ihs.gov/SelfGovernance.*

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If application budgets exceed the highest dollar amount outlined under the ''Estimated Funds Available'' section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, the IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

Tribal Resolution(s)

Submit Tribal resolution(s) from the appropriate governing body of the Indian Tribe to be served by the ISDEAA Compact authorizing the submission of a Negotiation Cooperative Agreement application. Tribal consortia applying for a TSGP Negotiation Cooperative Agreement shall submit Tribal Council resolutions from each Tribe in the consortium. Tribal resolutions can be attached to the electronic online application.

An official signed Tribal resolution must be received by the DGM prior to a Notice of Award (NoA) being issued to any applicant selected for funding. However, if an official signed Tribal resolution cannot be submitted with the electronic application submission prior to the official application deadline date, then a draft Tribal resolution is acceptable and must be submitted by the deadline in order for the application to be considered complete and eligible for review. The draft Tribal resolution is not in lieu of the required signed resolution, but is acceptable until a signed resolution is received. If an official signed Tribal resolution is not

received by DGM when funding decisions are made, then a (NoA) will not be issued to that applicant and they will not receive any IHS funds until such time as they have submitted a signed resolution to the Grants Management Specialist listed in this Funding Announcement.

An applicant submitting Tribal resolution(s) after the initial application submission due date is required to ensure the information was received by the IHS by obtaining documentation confirming delivery (*i.e.,* FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at: *http://www.Grants.gov* or *http://www.ihs.gov/dgm/funding/.*

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
  - SF–424, Application for Federal Assistance.
  - SF–424A, Budget Information—Non-Construction Programs.
  - SF–424B, Assurances—Non-Construction Programs.

Line Item Budget and Narrative (must be single-spaced and not exceed five pages).

- Project Narrative (must be single-spaced and not exceed ten pages).
  - Background information on the organization.
  - Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.
- Tribal Resolution(s).
- Letters of Support from organization's Board of Directors.
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) Financial Audit.

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
- Face sheets from audit reports.

These can be found on the FAC website: *https://harvester.census.gov/facdissem/Main.aspx.*

Public Policy Requirements

All Federal wide public policies apply to IHS grants and cooperative agreements with exception of the Discrimination Policy.

Requirements for Project and Budget Narratives

A. *Project Narrative:* This narrative should be a separate Word document that is not to exceed ten pages and must be single-spaced, type written, have consecutively numbered pages, use black type not smaller than 12 points, and be printed on one side only of standard size 8½″ x 11″ paper.

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation criteria in this announcement) and place all responses and required information in the correct section (noted below), or they will not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in becoming familiar with the applicant's activities and accomplishments prior to this possible cooperative agreement award. If the narrative exceeds the page limit, then only the first ten pages will be reviewed. The ten page limit for the narrative does not include the work plan, standard forms, Tribal resolutions, table of contents, budget, budget justifications, narratives, and/or other appendix items.

There are three parts to the narrative: Part A—Program Information; Part B—Program Planning and Evaluation; and Part C—Program Report. See below for additional details about what must be included in the narrative.

The page limitations below are for each narrative and budget submitted.

Part A: Program Information (4 page limit)

Section 1: Needs

Introduction and Need for Assistance

Demonstrate that the Tribe has conducted previous Self-Governance planning activities by clearly stating the results of what was learned during the planning process. Explain how the Tribe has determined it has the: (1) Knowledge and expertise to assume or expand PSFAs, and (2) the administrative infrastructure to support the assumption of PSFAs. Identify the need for assistance and how the Negotiation Cooperative Agreement would benefit the health activities the Tribe is preparing to assume or expand.

Part B: Program Planning and Evaluation (4 page limit)

Section 1: Program Plans

Project Objective(s), Work Plan and Approach

State in measureable terms the objectives and appropriate activities to achieve the following Negotiation Cooperative Agreement recipient award activities:

(A) Determine the PSFAs that will be negotiated into the Tribe's Compact and FA. Prepare and discuss each Program, Service, Function, and Activity in comparison to the current level of services provided so that an informed decision can be made on new or expanded program assumption.

(B) Identify Tribal shares associated with the PSFAs that will be included in the FA.

(C) Develop the terms and conditions that will be set forth in both the Compact and FA to submit to the ALN prior to negotiations.

(D) Describe fully and clearly how the Tribe's proposal will result in an improved approach to managing the PSFAs to be assumed or expanded. Include how the Tribe plans to demonstrate improved health services to the community and incorporate the proposed timelines for negotiations.

Organizational Capabilities, Key Personnel, and Qualifications

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

Section 2: Program Evaluation

Describe fully and clearly how the improvements that will be made by the Tribe to manage the health care system and identify the anticipated or expected benefits for the Tribe. Define the criteria to be used to evaluate objectives associated with the project.

Part C: Program Report (2 page limit)

Section 1: Describe major accomplishments over the last 24 months associated with the goals of this announcement. Please identify and describe significant health related

program accomplishments associated with the delivery of quality health services. This section should highlight major program achievements over the last 24 months.

Section 2: Describe major activities over the last 24 months. Please provide an overview of significant program activities associated with the delivery of quality health services over the last 24 months. This section should address significant program activities and include those related to the accomplishments listed in the previous section.

B. Budget Narrative (5 page limit)

This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable allowable, allocable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described in the project narrative.

3. Submission Dates and Times

Applications must be submitted electronically through *Grants.gov* by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact *Grants.gov* Customer Support via email to *support@grants.gov* or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Gettys (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Tribes can apply for a Planning Cooperative Agreement and a Negotiation Cooperative Agreement in the same cycle, so long as the project proposals are different for each application. Tribes cannot apply for both the Planning Cooperative Agreement and the Negotiation Cooperative Agreement within the same grant cycle with the same proposed project.
- Only one Negotiation grant/cooperative agreement will be awarded per applicant per grant cycle under this announcement.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the *http://www.Grants.gov* website to submit an application electronically and select the ''Search Grants'' link on the homepage. Follow the instructions for submitting an application under the Package tab. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

Waiver Request

If the applicant needs to submit a paper application instead of submitting electronically through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM, (see Section IV.6 below for additional information). A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov.* The waiver must: (1) Be documented in writing (emails are acceptable), before submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval must be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Director of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding. Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or *http://www.Grants.gov* registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in *http://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact *Grants.gov* support directly at: *support@grants.gov* or (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to fifteen working days.
- Please use the optional attachment feature in *Grants.gov* to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this funding announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The DGM will download the application from *Grants.gov* and provide necessary copies to the appropriate agency officials. Neither the DGM nor the OTSG will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site

may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, you may access it through *http://fedgov.dnb.com/webform,* or to expedite the process, call (866) 705–5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at: *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge. Applicants may register online at: *https://www.sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy website: *http://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The ten page narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 60 points is required for funding. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (25 points)

Demonstrate that the Tribe has conducted previous Self-Governance planning activities by clearly stating the results of what was learned during the planning process. Explain how the Tribe has determined it has the: (1) Knowledge and expertise to assume or expand PSFAs, and (2) the administrative infrastructure to support the assumption of PSFAs. Identify the need for assistance and how the Negotiation Cooperative Agreement would benefit the health activities the Tribe is preparing to assume or expand.

B. Project Objective(s), Work Plan and Approach (25 points)

State in measurable terms the objectives and appropriate activities to achieve the following Planning Cooperative Agreement recipient award activities:

(1) Determine the PSFAs that will be negotiated into the Tribe's Compact and FA. Prepare and discuss each Program, Service, Function and Activity in comparison to the level of services provided so that an informed decision can be made on new or expanded program assumption.

(2) Identify Tribal shares associated with the PSFAs that will be included in the FA.

(3) Develop the terms and conditions that will be set forth in both the Compact and FA to submit to the ALN prior to negotiations. Clearly describe how the Tribe's proposal will result in an improved approach to managing the PSFAs to be assumed or expanded. Include how the Tribe plans to demonstrate improved health care services to the community and incorporate the proposed timelines for negotiations.

C. Program Evaluation (25 points)

Describe fully the improvements that will be made by the Tribe to manage the health care system and identify the anticipated or expected benefits for the Tribe. Define the criteria to be used to evaluate objectives associated with the project.

D. Organizational Capabilities, Key Personnel and Qualifications (15 points)

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

E. Categorical Budget and Budget Justification (10 points)

Submit a budget with a narrative describing the budget request and matching the scope of work described in the project narrative. Justify all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative.

Additional documents can be uploaded as Appendix Items in *Grants.gov*:

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS Program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.,* budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The NoA is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (*https://www.grantsolutions.gov*). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/period of performance.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 60 and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the OTSG within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorized Organizational Representative that is identified on the face page (SF–424) of the application. The OTSG will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved but Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be ''Approved,'' but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2018 the approved but unfunded application may be re-considered by the OTSG for possible funding. The applicant will also receive an Executive Summary Statement from the OTSG within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of the IHS.

2. Administrative Requirements

Cooperative agreements are administered in accordance with the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75, located on the U.S. Government Publishing Office website at: *http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75.*

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07, located at: *http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.*

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' located at 45 CFR part 75, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of the Interior (Interior Business Center) *https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes.* For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under ''Agency Contacts'' or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a ''Grant Note'' in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually. These reports must include a brief comparison of actual accomplishments to the goals established for the six month period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required by the program office. A final report must be submitted within 90 days of expiration of the budget or period of performance.

B. Financial Reports

Federal Financial Report (FFR or SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at: *https://pms.psc.gov.* It is recommended that the applicant also send a copy of the FFR (SF–425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable

database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the period of performance is made up of more than one budget period) and where: (1) The period of performance start date was October 1, 2010 or after, and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy website at: *http://www.ihs.gov/dgm/policytopics/.*

D. Compliance With Executive Order 13166 Implementation of Services

Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see *http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/.*

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see *http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html;* and *http://www.hhs.gov/civil-rights/index.html.* Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see *http://www.hhs.gov/civil-rights/for-individuals/disability/index.html.* Please contact the HHS OCR for more information about obligations and prohibitions under Federal civil rights laws at: *https://www.hhs.gov/ocr/about-us/contact-us/index.html* or call (800) 368–1019 or TDD (800) 537–7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at: *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.*

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS.

Recipients will be required to sign the HHS–690 Assurance of Compliance form which can be obtained from the following website: *http://www.hhs.gov/sites/default/files/forms/hhs-690.pdf,* and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Avenue SW, Washington, DC 20201.

E. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System *(*FAPIIS*)* before making any award in excess of the simplified acquisition threshold (currently $150,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-Federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-Federal entity or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to:

U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, (Include ''Mandatory Grant Disclosures'' in subject line), Office: (301) 443–5204, Fax: (301) 594–0899, Email: *Robert.Tarwater@ihs.gov*.

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: *http://oig.hhs.gov/fraud/report-fraud/index.asp*, (Include ''Mandatory Grant Disclosures'' in subject line), Fax: (202) 205–0604 (Include ''Mandatory Grant Disclosures'' in subject line) or Email: *MandatoryGranteeDisclosures@oig.hhs.gov*.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Roxanne

Houston, Program Officer, Office of Tribal Self-Governance, 5600 Fishers Lane, Mail Stop: 08E05, Rockville, MD 20857, Phone: (301) 443–7821, Email: *Roxanne.Houston@ihs.gov*, website: *http://www.ihs.gov/self-governance*.

2. Questions on grants management and fiscal matters may be directed to: Vanietta Armstrong, Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–4792, Fax: (301) 594–0899, Email: *Vanietta.Armstrong@ihs.gov*.

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–2114; or the DGM main line (301) 443–5204, Fax: (301) 594–0899, Email: *Paul.Gettys@ihs.gov*.

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: April 5, 2018.

Michael D. Weahkee,

Assistant Surgeon General, U.S. Public Health Service, Acting Director, Indian Health Service.

[FR Doc. 2018–07941 Filed 4–16–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Tribal Self-Governance; Planning Cooperative Agreement

Announcement Type: New—Limited Competition

Funding Announcement Number: HHS–2018–IHS–TSGP–0001

Catalog of Federal Domestic Assistance Number: 93.444

Key Dates

Application Deadline Date: June 17, 2018

Review Date: June 25–29, 2018

Earliest Anticipated Start Date: July 15, 2018

Tribal Resolutions Due Date: June 17, 2018

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG), is accepting applications for Planning Cooperative Agreements for the Tribal Self-Governance Program (TSGP). This program is authorized under: Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5383(e). This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.444.

Background

The TSGP is more than an IHS program; it is an expression of the Government-to-Government relationship between the United States (U.S.) and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume Programs, Services, Functions, and Activities (PSFAs), or portions thereof, which gives Tribes the authority to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP affords Tribes the most flexibility to tailor health care PSFAs and is one of three ways that Tribes can choose to obtain health care from the Federal Government for their citizens. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS, (2) contract with the IHS to administer individual programs and services the IHS would otherwise provide (referred to as Title I Self-Determination Contracting, and (3) compact with the IHS to assume control over health care programs the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive and Tribes may choose to combine options based on their individual needs and circumstances.

The TSGP is a tribally driven initiative, and strong Federal-Tribal partnerships are essential to the program's success. The IHS established the OTSG to implement the self-governance authorities under the ISDEAA. The primary OTSG functions are to: (1) Serve as the primary liaison and advocate for Tribes participating in the TSGP, (2) develop, direct, and implement TSGP policies and procedures, (3) provide information and technical assistance to Self-Governance Tribes, and (4) advise the IHS Director on compliance with TSGP policies, regulations, and guidelines. Each IHS Area has an Agency Lead Negotiator (ALN), designated by the IHS Director to act on his or her behalf, who has authority to negotiate Self-Governance Compacts and Funding Agreements. Prospective Tribes interested in participating in the TSGP should contact their respective ALN to begin the Self-Governance planning process. Also, Tribes currently participating in the TSGP, who are interested in expanding existing or adding new PSFAs should also contact their respective ALN to discuss the best methods for expanding or adding new PSFAs.

Purpose

The purpose of this Planning Cooperative Agreement is to provide resources to Tribes interested in entering the TSGP and to existing Self-Governance Tribes interested in assuming new or expanded PSFAs. Title V of the ISDEAA requires a Tribe or Tribal organization to complete a planning phase to the satisfaction of the Tribe. The planning phase must include legal and budgetary research and internal Tribal government planning and organizational preparation relating to the administration of health care programs. See 25 U.S.C. 5383(d).

The planning phase is critical to negotiations and helps Tribes make informed decisions about which PSFAs to assume and what organizational changes or modifications are necessary to successfully support those PSFAs. A thorough planning phase improves timeliness and efficient negotiations and ensures that the Tribe is fully prepared to assume the transfer of IHS PSFAs to the Tribal health program.

A Planning Cooperative Agreement is not a prerequisite to enter the TSGP and a Tribe may use other resources to meet the planning requirement. Tribes that receive Planning Cooperative Agreements are not obligated to participate in the TSGP and may choose to delay or decline participation based on the outcome of their planning activities. This also applies to existing Self-Governance Tribes exploring the option to expand their current PSFAs or assume additional PSFAs.

Limited Competition Justification

There is limited competition under this announcement because the authorizing legislation restricts eligibility to Tribes that meet specific criteria identified in Section III. Eligibility Criteria, 1. Eligibility, A. See 25 U.S.C. 5383(e); 42 CFR 137.10 and §§ 137.24–26.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2018 is approximately $600,000. Individual award amounts are anticipated to be $120,000. The amount of funding available for awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately five awards will be issued under this program announcement.

Period of Performance

The period of performance is for one year and will run consecutively from July 15, 2018, to July 14, 2019.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. However, the IHS is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS and the grantee. The IHS will be responsible for activities listed under section A and the grantee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for Cooperative Agreement

A. IHS Programmatic Involvement

(1) Provide descriptions of PSFAs and associated funding at all organizational levels (service unit, area, and headquarters), including funding formulas and methodologies related to determining Tribal shares.

(2) Meet with Planning Cooperative Agreement recipients to provide program information and discuss methods currently used to manage and deliver health care.

(3) Identify and provide statutes, regulations, and policies that provide authority for administering IHS programs.

(4) Provide technical assistance on the IHS budget, Tribal shares, and other topics as needed.

B. Grantee Cooperative Agreement Award Activities

(1) Research and analyze the complex IHS budget to gain a thorough understanding of funding distribution at all organizational levels and to determine which PSFAs the Tribe may elect to assume or expand.

(2) Establish a process by which Tribes may approach the IHS to identify PSFAs and associated funding that may be incorporated into their current programs.

(3) Determine the Tribe's share of each Program, Service, Function and Activity and evaluate the current level of healthcare services being provided to make an informed decision on new or expanded program assumption(s).

III. Eligibility Information

1. Eligibility

To be eligible for the New Limited Competition Planning Cooperative Agreement under this announcement, an applicant must:

(A) Be an ''Indian Tribe'' as defined in 25 U.S.C. 5304(e); a ''Tribal Organization'' as defined in 25 U.S.C. 5304(l); or an ''Inter-Tribal Consortium: As defined at 42 CFR 137.10. However, Alaska Native Villages or Alaska Native Village Corporations are not eligible if they are located within the area served by an Alaska Native regional health entity. See Consolidated Appropriations Act, 2014, Public Law 113–76. By statute, the Native Village of Eyak, Eastern Aleutian Tribes, and the Council for Athabascan Tribal Governments have also been deemed Alaska Native regional health entities and therefore are eligible to apply. Those Alaska Tribes not represented by a Self-Governance Tribal consortium Funding Agreement within their area may still be considered to participate in the TSGP.

(B) Submit Tribal resolution(s) from the appropriate governing body of each Indian Tribe to be served by the ISDEAA Compact authorizing the submission of the Planning Cooperative Agreement. Tribal consortia applying for a Planning Cooperative Agreement shall submit Tribal Council resolutions from each Tribe in the consortium. Tribal resolutions can be attached to the electronic online application.

(C) Demonstrate for three fiscal years, financial stability and financial management capability. The Indian Tribe must provide evidence that, for the three fiscal years prior to requesting participation in the TSGP, the Indian Tribe has had no uncorrected significant and material audit exceptions in the required annual audit of the Indian Tribe's Self-Determination Contracts or Self-Governance Funding Agreements with any Federal Agency. See 25 U.S.C. 5383; 42 CFR 137.15–23.

For Tribes or Tribal organizations (T/TO) that expended $750,000 or more ($500,000 for fiscal years ending after December 31, 2003) in Federal awards, the OTSG shall retrieve the audits directly from the Federal Audit Clearinghouse.

For T/TO that expended less than $750,000 ($500,000 for fiscal years ending after December 31, 2003) in Federal awards, the T/TO must provide evidence of the program review correspondence from IHS or Bureau of Indian Affairs officials. *See* 42 CFR 137.21–23.

Meeting the eligibility criteria for a Planning Cooperative Agreement does not mean that a Tribe/Tribal Organization is eligible for participation in the IHS TSGP under Title V of the ISDEAA. See 25 U.S.C. 5383; 42 CFR 137.15–23. For additional information on the eligibility for the IHS TSGP, please visit the ''Eligibility and Funding'' page on the OTSG website located at: *http://www.ihs.gov/SelfGovernance.*

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If application budgets exceed the highest dollar amount outlined under the ''Estimated Funds Available'' section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

Tribal Resolution(s)

Submit Tribal resolution(s) from the appropriate governing body of the Indian Tribe to be served by the ISDEAA Compact authorizing the submission of a Negotiation Cooperative Agreement application. Tribal consortia applying for a TSGP Negotiation Cooperative Agreement shall submit Tribal Council resolutions from each Tribe in the consortium. Tribal

resolutions can be attached to the electronic online application.

An official signed Tribal resolution must be received by the DGM prior to a Notice of Award (NoA) being issued to any applicant selected for funding. However, if an official signed Tribal resolution cannot be submitted with the electronic application submission prior to the official application deadline date, then a draft Tribal resolution is acceptable and must be submitted by the deadline in order for the application to be considered complete and eligible for review. The draft Tribal resolution is not in lieu of the required signed resolution, but is acceptable until a signed resolution is received. If an official signed Tribal resolution is not received by DGM when funding decisions are made, then a NoA will not be issued to that applicant and they will not receive any IHS funds until such time as they have submitted a signed resolution to the Grants Management Specialist listed in this funding announcement.

An applicant submitting Tribal resolution(s) after the initial application submission due date is required to ensure the information was received by the IHS by obtaining documentation confirming delivery (*i.e.,* FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at: *http://www.Grants.gov* or *http://www.ihs.gov/dgm/funding/.*

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
  - SF–424, Application for Federal Assistance.
  - SF–424A, Budget Information—Non-Construction Programs.
  - SF–424B, Assurances—Non-Construction Programs.
- Line Item Budget and Narrative (must be single-spaced and not exceed five pages).
- Project Narrative (must be single-spaced and not exceed ten pages).
  - Background information on the organization.
  - Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.
- Tribal Resolution(s).
- Letters of Support from organization's Board of Directors.
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) Financial Audit.

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
- Face sheets from audit reports. These can be found on the FAC website: *https://harvester.census.gov/facdissem/Main.aspx.*

Public Policy Requirements:

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the Discrimination Policy.

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative should be a separate Word document that is not to exceed ten pages and must be single-spaced, type written, have consecutively numbered pages, use black type not smaller than 12 characters per one inch, and be printed on one side only of standard size 8½″ x 11″ paper.

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation criteria in this announcement) and place all responses and required information in the correct section (noted below), or they will not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in becoming familiar with the applicant's activities and accomplishments prior to this possible cooperative agreement award. If the narrative exceeds the page limit, then only the first ten pages will be reviewed. The ten page limit for the narrative does not include the work plan, standard forms, Tribal resolutions, table of contents, budget, budget justifications, narratives, and/or other appendix items.

There are three parts to the narrative: Part A—Program Information; Part B—Program Planning and Evaluation; and Part C—Program Report. See below for additional details about what must be included in the narrative.

The page limitations below are for each narrative and budget submitted.

Part A: Program Information (4 Page Limit)

Section 1: Needs

Describe the Tribe's current health program activities, including: How long it has been operating, what programs or services are currently being provided, and if the applicant is currently administering any ISDEAA Title I Self-Determination Contracts or Title V Self-Governance Compacts. Identify the need for assistance and how the Planning Cooperative Agreement would benefit the health activities the Tribe is currently administering or looking to expand.

Part B: Program Planning and Evaluation (4 Page Limit)

Section 1: Program Plans

Project Objective(s), Work Plan and Approach

State in measureable terms the objectives and appropriate activities to achieve the following Planning Cooperative Agreement recipient award activities:

(A) Research and analyze the complex IHS budget to gain a thorough understanding of funding distribution at all organizational levels and determine which PSFAs the Tribe may elect to assume or expand.

(B) Establish a process to identify PSFAs and associated funding that may be incorporated into current programs.

(C) Determine the Tribe's share of each Program, Service, Function and Activity and evaluate the current level of health care services being provided to make an informed decision on new or expanded program assumption.

(D) Describe how the objectives are consistent with the purpose of the program, the needs of the people to be served, and how they will be achieved within the proposed time frame. Identify the expected results, benefits, and outcomes or products to be derived from each objective of the project.

Organizational Capabilities, Key Personnel, and Qualifications

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or

position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

Section 2: Program Evaluation

Define the criteria to be used to evaluate planning activities. Describe fully and clearly the methodology that will be used to determine if the needs identified are being met and if the outcomes are being achieved. This section must address the following questions:

(A) Are the goals and objectives measurable and consistent with the purpose of the program and the needs of the people to be served?

(B) Are they achievable within the proposed time frame?

Part C: Program Report (2 Page Limit)

Section 1: Describe major accomplishments over the last 24 months associated with the goals of this announcement. Please identify and describe significant health related program activities and achievements associated with the delivery of quality health services. Provide a comparison of the actual accomplishments to the goals established for the period of performance, or if applicable, provide justification for the lack of progress. This section should highlight major program achievements over the last 24 months.

Section 2: Describe major activities over the last 24 months. Please provide an overview of significant program activities associated with the delivery of quality health services over the last 24 months. This section should address significant program activities and include those related to the accomplishments listed in the previous section.

B. Budget Narrative (5 Page Limit)

This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable allowable, allocable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described in the project narrative.

3. Submission Dates and Times

Applications must be submitted electronically through *Grants.gov* by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact *Grants.gov* Customer Support via email to *support@grants.gov* or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Gettys (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Tribes can apply and be awarded both a Planning Cooperative Agreement and a Negotiation Cooperative Agreement in the same cycle, so long as the project proposals are different for each application. Tribes cannot apply for both the Planning Cooperative Agreement and the Negotiation Cooperative Agreement within the same grant cycle with the same proposed project.
- Only one Planning grant/cooperative agreement will be awarded per applicant per grant cycle under this announcement.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the *http://www.Grants.gov* website to submit an application electronically and select the ''Find Grant Opportunities'' link on the homepage. Follow the instructions for submitting an application under the Package tab. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

Waiver Request

If the applicant needs to submit a paper application instead of submitting electronically through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM, (see Section IV.6 below for additional information). A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov*. The waiver must: (1) Be documented in writing (emails are acceptable), before submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval must be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Director of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding. Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or *http://www.Grants.gov* registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in *http://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact *Grants.gov* support directly at: *support@grants.gov* or (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for

SAM and *Grants.gov* could take up to fifteen working days.

- Please use the optional attachment feature in *Grants.gov* to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this funding announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The DGM will download the application from *Grants.gov* and provide necessary copies to the appropriate agency officials. Neither the DGM nor the OTSG will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, you may access it through *http://fedgov.dnb.com/webform,* or to expedite the process, call (866) 705–5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at: *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge. Applicants may register online at: *https://www.sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy website: *http://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The ten page narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 60 points is required for funding. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (25 Points)

Describe the Tribe's current health program activities, including: How long it has been operating, what programs or services are currently being provided, and if the applicant is currently administering any ISDEAA Title I Self-Determination Contracts or Title V Self-Governance Compacts. Identify the need for assistance and how the Planning Cooperative Agreement would benefit the health activities the Tribe is currently administering and/or looking to expand.

B. Project Objective(s), Work Plan and Approach (25 Points)

State in measurable terms the objectives and appropriate activities to achieve the following Planning Cooperative Agreement recipient award activities:

(1) Research and analyze the complex IHS budget to gain a thorough understanding of funding distribution at all organizational levels and determine which PSFAs the Tribe may elect to assume or expand.

(2) Establish a process to identify PSFAs and associated funding that may be incorporated into current programs.

(3) Determine the Tribe's share of each Program, Service, Function and Activity and evaluate the current level of health care services being provided to make an informed decision on new or expanded program assumption.

(4) Describe how the objectives are consistent with the purpose of the program, the needs of the people to be served, and how they will be achieved within the proposed time frame. Identify the expected results, benefits, and outcomes or products to be derived from each objective of the project.

C. Program Evaluation (25 Points)

Define the criteria to be used to evaluate planning activities. Clearly describe the methodologies and parameters that will be used to determine if the needs identified are being met and if the outcomes identified are being achieved. Are the goals and objectives measurable and consistent with the purpose of the program and meet the needs of the people to be served? Are they achievable within the proposed time frame? Describe how the assumption of PSFAs enhances sustainable health delivery. Ensure the measurement includes activities that will lead to sustainability.

D. Organizational Capabilities, Key Personnel and Qualifications (15 Points)

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

E. Categorical Budget and Budget Justification (10 Points)

Submit a budget with a narrative describing the budget request and matching the scope of work described in the project narrative. Justify all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative.

Additional Documents Can Be Uploaded as Appendix Items in *Grants.gov*

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.

• Map of area identifying project location(s).

• Additional documents to support narrative (*i.e.* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS Program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.,* budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The NoA is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (*https://www.grantsolutions.gov*). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/period of performance.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 60 and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the OTSG within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorized Organizational Representative that is identified on the face page (SF–424) of the application. The OTSG will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be ''Approved,'' but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2018 the approved but unfunded application may be re-considered by the OTSG for possible funding. The applicant will also receive an Executive Summary Statement from the OTSG within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of the IHS.

2. Administrative Requirements

Cooperative agreements are administered in accordance with the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

• Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75, located on the U.S. Government Publishing Office website at: *http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75.*

C. Grants Policy:

• HHS Grants Policy Statement, Revised 01/07 located at: *http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.*

D. Cost Principles:

• Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' located at 45 CFR part 75, subpart E.

E. Audit Requirements:

• Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of Interior (Interior Business Center) *https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes.* For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under ''Agency Contacts'' or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions, and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a ''Grant Note'' in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually. These reports must include a brief comparison of actual accomplishments to the goals established for the six month period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required by the program office. A final report must be submitted within 90 days of expiration of the budget or period of performance.

B. Financial Reports

Federal Financial Report (FFR or SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at: *https://pms.psc.gov.* It is recommended that the applicant also send a copy of the FFR (SF–425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the period of performance is made up of more than one budget period) and where: (1) The period of performance start date was October 1, 2010, or after, and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy website at: *http://www.ihs.gov/dgm/policytopics/.*

D. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see *http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/.*

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see *http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html;* and *http://www.hhs.gov/civil-rights/index.html.* Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see *http://www.hhs.gov/civil-rights/for-individuals/disability/index.html.* Please contact the HHS OCR for more information about obligations and prohibitions under Federal civil rights laws at: *https://www.hhs.gov/ocr/about-us/contact-us/index.html* or call (800) 368–1019 or TDD (800) 537–7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at: *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.*

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS.

Recipients will be required to sign the HHS–690 Assurance of Compliance form which can be obtained from the following website: *http://www.hhs.gov/sites/default/files/forms/hhs-690.pdf,* and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Avenue SW, Washington, DC 20201.

E. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS) before making any award in excess of the simplified acquisition threshold (currently $150,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-Federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-Federal entity or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal

law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to:

U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857. (Include ''Mandatory Grant Disclosures'' in subject line). Office: (301) 443–5204, Fax: (301) 594–0899, Email: *Robert.Tarwater@ihs.gov*

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: *http://oig.hhs.gov/fraud/report-fraud/index.asp.* (Include ''Mandatory Grant Disclosures'' in subject line). Fax: (202) 205–0604 (Include ''Mandatory Grant Disclosures'' in subject line) or Email: *MandatoryGrantee Disclosures@oig.hhs.gov*

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Roxanne Houston, Program Officer, Office of Tribal Self-Governance, 5600 Fishers Lane, Mail Stop: 08E05, Rockville, MD 20857, Phone: (301) 443–7821, Email: *Roxanne.Houston@ihs.gov*, Website: *http://www.ihs.gov/self-governance*.

2. Questions on grants management and fiscal matters may be directed to: Vanietta Armstrong, Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–4792, Fax: 301–594–0899, Email: *Vanietta.Armstrong@ihs.gov*.

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443–2114; or the DGM main line (301) 443–5204, Fax: (301) 594–0899, E-Mail: *Paul.Gettys@ihs.gov*.

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: April 5, 2018.

Michael D. Weahkee,

Assistant Surgeon General, U.S. Public Health Service, Acting Director, Indian Health Service.

[FR Doc. 2018–07942 Filed 4–16–18; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: May 9, 2018.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Susana Mendez, DVM, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G53B, National Institutes of Health, NIAID, 5601 Fishers Lane Dr., MSC 9823, Bethesda, MD 20892–9823, (240) 669–5077, *mendezs@niaid.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: May 9, 2018.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Susana Mendez, DVM, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G53B, National Institutes of Health, NIAID, 5601 Fishers Lane Dr., MSC 9823, Bethesda, MD 20892–9823, (240) 669–5077, *mendezs@niaid.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: May 10, 2018.

Time: 8:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Annie Walker-Abbey, Ph.D., Scientific Review Officer, Scientific Review Program, NIAID/NIH/DHHS, 5601 Fishers Lane, Room 3E70A, Rockville, MD 20852, 240–627–3390, *aabbey@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 11, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–07915 Filed 4–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases Notice of Closed 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: May 8, 2018.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Annie Walker-Abbey, Ph.D., Scientific Review Officer, Scientific Review Program, NIAID/NIH/DHHS, 5601 Fishers Lane, Room 3E70A, Rockville, MD 20852, 240–627–3390, *aabbey@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; AIDSRRC Independent SEP.

Date: May 8, 2018.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Audrey O. Lau, Ph.D., MPH, Scientific Review Officer, AIDS Review Branch, SRP, RM 3E70, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9834, Rockville, MD 20852–9834, 240–669–2081, *audrey.lau@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 11, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–07914 Filed 4–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Dental and Craniofacial Research Council.

Date: May 25, 2018.

Open: 8:30 a.m. to 12:20 p.m.

Agenda: Report to the Director, NIDCR.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Closed: 1:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Alicia J. Dombroski, Ph.D., Director, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892, 301–594–4805, *adombroski@nidcr.nih.gov.*

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.nidcr.nih.gov/about,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: April 11, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–07917 Filed 4–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Dental and Craniofacial Research, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

Date: May 8–10, 2018.

Time: May 8, 2018, 7:00 p.m. to 8:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Time: May 9, 2018, 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 30, Room 117, 30 Center Drive, Bethesda, MD 20892.

Time: May 10, 2018, 8:00 a.m. to 4:15 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 30, Room 117, 30 Center Drive, Bethesda, MD 20892.

Contact Person: Alicia J. Dombroski, Ph.D., Director, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892.

Information is also available on the Institute's/Center's home page: *http://www.nidcr.nih.gov/about/CouncilCommittees.asp,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: April 11, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–07916 Filed 4–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meetings

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the Task Force on Research Specific to Pregnant Women and Lactating Women.

The meetings will be open to the public, with attendance limited to space available. Individuals who plan to

attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Task Force on Research Specific to Pregnant Women and Lactating Women.

Date: May 14–15, 2018.

Time: May 14, 2018 8:30 a.m. to 5:00 p.m., May 15, 2018 8:00 a.m. to 2:30 p.m.

Agenda: The Task Force is charged with providing advice and guidance to the Secretary of HHS, regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.

Place: 6710B Rockledge Drive, Room 1425/1427 (1st Floor), Bethesda, MD 20817.

Contact Person: Ms. Lisa Kaeser, Executive Secretary, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 31 Center Drive, Room 2A03, MSC 2425, Bethesda, MD 20892, (301) 496–0536, *kaeserl@mail.nih.gov.*

Public comments are welcome either by filing written comments and/or providing oral comments at the meeting. Oral comments from the public will be scheduled on May 14, 2018, from approximately 10:00 a.m.–10:45 a.m. Any member of the public interested in presenting oral comments on May 14, 2018, should submit a letter of intent, a brief description of the organization represented, and the oral presentation to Ms. Lisa Kaeser (*Kaeserl@mail.nih.gov*) by 5:00 p.m. on Monday, May 7, 2018. Written comments to be included at the meeting should also be sent to Lisa Kaeser by 5:00 p.m. on Monday, May 7, 2018.

The submitted presentations and any written comments will be formatted to be posted on the PRGLAC website for the record. Only one representative of an organization may be allowed to present oral comments. Presentations will be limited to three to five minutes per speaker depending on the number of speakers to be accommodated within the allotted time. Speakers will be assigned a time to speak in the order of the date and time when their request to speak is received. Both printed and electronic copies are requested for the record.

Details and additional information about these meetings can be found at the NICHD website for the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) *https://www.nichd.nih.gov/about/advisory/PRGLAC/Pages/index.aspx.*

Dated: April 11, 2018.

Michelle D. Trout,

Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–07918 Filed 4–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc., as a Commercial Gauger and Laboratory

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

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Camin Cargo Control, Inc., has been approved to gauge and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of July 6, 2017.

DATES: The accreditation and approval of Camin Cargo Control, Inc., as commercial gauger and laboratory became effective on July 6, 2017. The next triennial inspection date will be scheduled for July 2020.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Cassata, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Camin Cargo Control, Inc., 1301 Metropolitan Ave., Thorofare, NJ 08086, has been approved to gauge and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Camin Cargo Control, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
11	Physical Property.
12	Calculations.
17	Maritime Measurements.

Camin Cargo Control, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	Method	Title
27–08	ASTM D86	Standard Test Method for Distillation of Petroleum Products.
27–48	ASTM D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–58	ASTM D5191	Standard Test Method For Vapor Pressure of Petroleum Products (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the website listed below for the current CBP Approved Gaugers and Accredited Laboratories List. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: April 10, 2018.

James D. Sweet,

Acting Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2018–07969 Filed 4–16–18; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

Approval of Intertek USA, Inc., as a Commercial Gauger

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

ACTION: Notice of approval of Intertek USA, Inc., as a commercial gauger.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that

Intertek USA, Inc., has been approved to gauge petroleum and certain petroleum products for customs purposes for the next three years as of September 20, 2017.

DATES: The approval of Intertek USA, Inc., as commercial gauger became effective on September 20, 2017. The next triennial inspection date will be scheduled for September 2020.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Cassata, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.13, that Intertek USA, Inc., 1020 South Holland Sylvania Rd., Holland, OH 43528, has been approved to gauge petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.13. Intertek USA, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API chapters	Title
2	Tank Calibration.
3	Tank gauging.
7	Temperature Determination.
8	Sampling.
12	Calculations.
14	Natural Gas Fluids Measurements.
17	Maritime Measurements.

Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: April 10, 2018.

James D. Sweet,

Acting Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2018–07975 Filed 4–16–18; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0024]

Agency Information Collection Activities: Entry/Immediate Delivery Application and ACE Cargo Release

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; revision and extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection 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 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted (no later than June 18, 2018) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0024 in the subject line and the agency name. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Email. Submit comments to: CBP_PRA@cbp.dhs.gov.*

(2) *Mail.* Submit written comments to CBP Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 90 K Street NE, 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number (202) 325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (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, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions 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, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Entry/Immediate Delivery Application and ACE Cargo Release.

OMB Number: 1651–0024.

Form Number: 3461 and 3461 ALT.

Current Actions: This submission is being made to extend the expiration date with a change in the data collected. There is an increase to the annual burden hours based on updated agency estimates. Since the last OMB Renewal there have been two submissions for a Non Substantive Change for this information collection. The Non Substantive Changes made are the following:

Change one submitted on February 22, 2018: CBP is submitting this Non Substantive Change to OMB to reflect a change in the Harmonized Tariff Schedule (HTS) which is maintained by the U.S. International Trade Commission (USITC). HTS data is provided to CBP at entry.

Effective February 7, 2018, the following changes to the Harmonized Tariff Schedule for units of quantity reporting will take effect:

- For HTS 8450.90.20 and 8450.90.60, certain parts of washing machines, the new unit of quantity will be ''No.'' instead of ''X''.

• For HTS 8541.40.6030, solar cells, a second unit of quantity, ''W'' (for total wattage), will be added.

• For statistical reporting purposes under subheading 8541.40.6030, importers should report the total watts at maximum power based on standard test conditions according to the latest revision of International Electrotechnical Commission (IEC) 60904, ''Photovoltaic Devices.''

• These modifications will take effect as announced in Presidential Proclamations 9693 (83 FR 3541) and 9694 (83 FR 3553), of January 23, 2018.

For additional information regarding the HTS please follow this link: *https://hts.usitc.gov/current*

Change two submitted on March 19, 2018: CBP is submitting this Non Substantive change to reflect an adjustment in ACE Cargo due to U.S. Department of Commerce Bureau of Industry and Security (BIS) for Procedures for Submitting Requests for Exclusions from the Section 232 National Security Adjustments of Imports of Steel and Aluminum information collection. Importers who have submitted for exclusion from Section 232 shall submit the BIS exclusion number in the additional importer declaration field. This collection is authorized by 15 CFR 705, *https://www.gpo.gov/fdsys/pkg/CFR-2016-title15-vol2/pdf/CFR-2016-title15-vol2-part705.pdf*

Type of Review: Extension and Revision (with change)

Abstract: All items imported into the United States are subject to examination before entering the commerce of the United States. There are two procedures available to effect the release of imported merchandise, including ''entry'' pursuant to 19 U.S.C. 1484, and ''immediate delivery'' pursuant to 19 U.S.C. 1448(b). Under both procedures, CBP Forms 3461, Entry/Immediate Delivery, and 3461 ALT are the source documents in the packages presented to Customs and Border Protection (CBP). The information collected on CBP Forms 3461 and 3461 ALT allow CBP officers to verify that the information regarding the consignee and shipment is correct and that a bond is on file with CBP. CBP also uses these forms to close out the manifest and to establish the obligation to pay estimated duties in the time period prescribed by law or regulation. CBP Form 3461 is also a delivery authorization document and is given to the importing carrier to authorize the release of the merchandise.

CBP Forms 3461 and 3461 ALT are provided for by 19 CFR 141 and 142. These forms and instructions for Form 3461 are accessible at: *http://www.cbp.gov/newsroom/publications/forms*

ACE Cargo Release is a program for ACE entry summary filers in which importers or brokers may file Simplified Entry data in lieu of filing the CBP Form 3461. This data consists of 12 required elements: Importer of record; buyer name and address; buyer employer identification number (consignee number), seller name and address; manufacturer/supplier name and address; Harmonized Tariff Schedule 10-digit number; country of origin; bill of lading; house air waybill number; bill of lading issuer code; entry number; entry type; and estimated shipment value. Three optional data elements are the container stuffing location; consolidator name and address, and ship to party name and address. The data collected under the ACE Cargo Release program is intended to reduce transaction costs, expedite cargo release, and enhance cargo security. ACE Cargo Release filing minimizes the redundancy of data submitted by the filer to CBP through receiving carrier data from the carrier. This design allows the participants to file earlier in the transportation flow. Guidance on using ACE Cargo Release may be found at *http://www.cbp.gov/trade/ace/features.*

Affected Public: Businesses

CBP Form 3461 paper form only:

Estimated Number of Respondents: 12,307.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 12,307.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 3,077.

ACE Cargo Release to include electronic submission for 3461/3461ALT:

Estimated Number of Respondents: 9,810.

Estimated Number of Responses per Respondent: 2,994.

Estimated Total Annual Responses: 29,371,140.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 4,875,609.

Dated: April 12, 2018.

Seth D Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2018–08029 Filed 4–16–18; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7001–N–10]

30-Day Notice of Proposed Information Collection: Mortgagor's Certificate of Actual Cost

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* May 17, 2018.

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: Inez C. Downs, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email *Inez.C.Downs@hud.gov,* or telephone 202–402–8046. 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. Downs.

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 January 16, 2018.

A. Overview of Information Collection

Title of Information Collection: Mortgagor's Certificate of Actual Cost.

OMB Approved Number: 2502–0112.

Type of Request: Extension of currently approved collection.

Form Number: HUD–92330.

Description of the need for the information and proposed use: HUD uses form to obtain data from a mortgagor relative to actual cost of a

project. HUD uses the cost information to determine the maximum insurable mortgage for final endorsement of an insured mortgage. Actual cost is defined in Section 227c of the National Housing Act. In addition, form HUD–92330 must be accompanied by an audited balance sheet certified by Certified Public Accountant unless the project has less than 40 units, or if it is a refinancing or a purchase of an existing project under 207/223f or 232/223f.

Respondents: 1,206.

Estimated Number of Respondents: 1.

Estimated Number of Responses: 1,206.

Frequency of Response: 1.

Average Hours per Response: 8.

Total Estimated Burdens: 9,648.

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.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: April 4, 2018.

Inez C. Downs,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2018–07936 Filed 4–16–18; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7001–N–11]

30-Day Notice of Proposed Information Collection: Energy Efficient Mortgages (EEMs)

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* May 17, 2018.

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: Colette Pollard, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email *Colette_Pollard@hud.gov,* or telephone 202–402–3400. 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. Pollard.

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 February 7, 2018 at 83 FR 5455.

A. Overview of Information Collection

Title of Information Collection: Energy Efficient Mortgages (EEMs).

OMB Approval Number: 2502–0561.

Type of Request: Extension of currently approved collection.

Form Number: None.

Description of the Need for the Information and Proposed Use: Lenders provide the required information to determine the eligibility of a mortgage to be insured under Section 513 of the Housing and Community Development Act of 1992 (Section 106 of the Energy Policy Act of 1992). Section 2123 of the Housing and Economic Recovery Act of 2008 (HERA) (Pub. L. 110–289, approved July 30, 2008) amended Section 106 of the Energy Policy Act of 1992 by revising the maximum dollar amount that can be added to an FHA-insured mortgage for energy efficient improvements.

Respondents: (*i.e.,* affected public): Business or other for-profit (lenders).

Estimated Number of Respondents: 50.

Estimated Number of Responses: 420.

Frequency of Response: 8.40.

Average Hours per Response: 4.25.

Total Estimated Burdens: 1,785 hours.

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.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: April 5 2018.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2018–07935 Filed 4–16–18; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6068–D–02]

Redelegation of Authority to the General Deputy Assistant Secretary for Administration

AGENCY: Office of the Assistant Secretary for Administration, HUD.

ACTION: Notice of redelegation of authority.

SUMMARY: Through this notice, the Assistant Secretary for Administration redelegates to the General Deputy Assistant Secretary for Administration concurrent authority, vested in or delegated or assigned to the Assistant Secretary for Administration, including authority and responsibility for the coordination, management and

supervision for the following offices: Chief Human Capital Officer, Chief Procurement Officer, and Chief Administrative Officer.

DATES: This redelegation of authority is applicable upon signature.

FOR FURTHER INFORMATION CONTACT: John B. Shumway, Assistant General Counsel for Administrative Law, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 9262, Washington, DC 20410–0500, telephone number 202–402–5190. (This is not a toll-free number.) Individuals with speech or hearing impairments may access this number through TTY by calling 1–800–877–8339.

SUPPLEMENTARY INFORMATION: In January 2018, the Deputy Secretary delegated authority to the Assistant Secretary for Administration, which was published in the **Federal Register** at 83 FR 3764. In that notice, the Assistant Secretary for Administration was authorized to redelegate to employees of HUD the authority delegated by the Deputy Secretary. Through this notice, the Assistant Secretary for Administration hereby redelegates to the General Deputy Assistant Secretary for Administration concurrent authority, vested in or delegated or assigned to the Assistant Secretary for Administration including the authority to coordinate, manage and supervise the activities of the offices of the Chief Human Capital Officer, the Chief Procurement Officer, and the Chief Administrative Officer. This redelegation of authority does not include the authority to perform the duties and functions of the Chief Acquisition Officer, which was provided to the Assistant Secretary for Administration and, if the Assistant Secretary for Administration position is vacant, the Senior Procurement Executive in a designation published in the **Federal Register** at 83 FR 3765.

Section A. Authority

The Assistant Secretary for Administration hereby redelegates to the General Deputy Assistant Secretary for Administration the concurrent authority to coordinate, manage and supervise the activities of the following offices and functions:

1. *Office of the Chief Human Capital Officer:* This office is responsible for employee performance management; executive resources; human capital headquarters and field support; human capital policy; planning and training; recruitment and staffing; personnel security; employee assistance program; health and wellness; employee and labor relations; pay; benefits and retirement; and human capital information systems. More detailed information can be found in the delegation of authority notice for the Chief Human Capital Officer, posted at *https://www.hud.gov/sites/documents/5562-D-01_DELEGATION.PDF.*

2. *Office of the Chief Procurement Officer:* This office is responsible for obtaining all contracted goods and services required by the Department efficiently and in the most cost-effective manner possible to enable the Department to meet its strategic objectives. The office provides logistical support to HUD's program offices and other support offices in meeting their mission needs and provides leadership on developing fundamentally sound business practices. This redelegation does not include the authority to perform the duties and functions of the Chief Acquisition Officer, which was provided to the Assistant Secretary for Administration and, if the Assistant Secretary for Administration position is vacant, the Senior Procurement Executive in a designation notice published in the **Federal Register** at 83 FR 3765. The functions of the Chief Acquisition Officer are outlined at 41 U.S.C. 1702.

3. *Office of the Chief Administrative Officer:* This office is responsible for headquarters and field support services, Executive Secretariat and compliance functions (including privacy, records, and Freedom of Information Act compliance), facilities management, disaster management, national security, security of the Secretary, Deputy Secretary, and of the various HUD buildings, and communication support services, including digital and multimedia. More detailed information can be found in the delegation of authority notice for the Chief Administrative Officer, posted at *https://www.hud.gov/sites/documents/DOAADMIN071814.PDF.*

Section B. Authority to Redelegate

The General Deputy Assistant Secretary for Administration is authorized to redelegate to employees of HUD any of the authority delegated under Section A above.

Section C. Authority Superseded

This delegation does not supersede the previous delegation of authority from the Deputy Secretary to the Assistant Secretary of Administration, which was published in the **Federal Register** at 83 FR 3764.

Authority: Section 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: April 10, 2018.

Suzanne Israel Tufts,

Assistant Secretary for Administration.

[FR Doc. 2018–07921 Filed 4–11–18; 4:15 pm]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2018–0012; 189E1700D2 ET1SF0000.PSB000.EEEE500000; OMB Control Number 1014–0005]

Agency Information Collection Activities; Relief or Reduction in Royalty Rates

AGENCY: Bureau of Safety and Environmental Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Safety and Environmental Enforcement (BSEE) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before June 18, 2018.

ADDRESSES: Send your comments on this information collection request (ICR) by either of the following methods listed below:

- Electronically go to *http://www.regulations.gov.* In the Search box, enter BSEE–2018–0012 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- Email *kelly.odom@bsee.gov,* fax (703) 787–1546, or mail or hand-carry comments to the Department of the Interior; Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch; ATTN: Kelly Odom; 45600 Woodland Road, Sterling, VA 20166. Please reference OMB Control Number 1014–0005 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Kelly Odom by email at *kelly.odom@bsee.gov* or by telephone at (703) 787–1775.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection

requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comments addressing the following issues: (1) Is the collection necessary to the proper functions of BSEE; (2) Will this information be processed and used in a timely manner; (3) Is the estimate of burden accurate; (4) How might BSEE enhance the quality, utility, and clarity of the information to be collected; and (5) How might BSEE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The regulations at 30 CFR part 203, concern relief or reduction in royalty rates and are the subject of this collection. This request also covers any related Notices to Lessees and Operators (NTLs) that BSEE issues to clarify, supplement, or provide additional guidance on some aspects of our regulations.

The BSEE uses the information to make decisions on the economic viability of leases requesting a suspension or elimination of royalty or net profit share. These decisions have enormous monetary impact on both the lessee and the Federal Government. Royalty relief can lead to increased production of natural gas and oil, creating profits for lessees, and royalty and tax revenues for the Federal Government that they might not otherwise receive. We could not make an informed decision without the collection of information required by 30 CFR part 203.

Title of Collection: 30 CFR part 203, *Relief or Reduction in Royalty Rates.*

OMB Control Number: 1014–0005.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Potential respondents comprise Federal OCS oil, gas, and sulfur lessees/operators.

Total Estimated Number of Annual Respondents: Varies, not all of the potential respondents will submit information in any given year and some may submit multiple times.

Total Estimated Number of Annual Responses: 16.

Estimated Completion Time per Response: Varies from 1 hour to 2,000 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 724.

Respondent's Obligation: Most responses are mandatory, while others are required to obtain or retain benefits.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: We have identified application and audit fees; as well as an independent certified public accountant report. The non-hour cost burdens associated with this collection of information amount to $27,950.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Dated: March 15, 2018.

Doug Morris,

Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2018–07974 Filed 4–16–18; 8:45 am]

BILLING CODE 4310–VH–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2018–0010; 189E1700D2 ET1SF0000.PSB000.EEEE500000; OMB Control Number 1014–0008]

Agency Information Collection Activities; Well Control and Production Safety Training

AGENCY: Bureau of Safety and Environmental Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Safety and Environmental Enforcement (BSEE) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before June 18, 2018.

ADDRESSES: Send your comments on this information collection request (ICR) by either of the following methods listed below:

- Electronically go to *http://www.regulations.gov.* In the Search box, enter BSEE–2018–0010 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- Email *kye.mason@bsee.gov,* fax (703) 787–1546, or mail or hand-carry comments to the Department of the Interior; Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch; ATTN: Nicole Mason; 45600 Woodland Road, Sterling, VA 20166. Please reference OMB Control Number 1014–0008 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Nicole Mason by email at *kye.mason@bsee.gov* or by telephone at (703) 787–1607.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comments addressing the following issues: (1) Is the collection necessary to the proper functions of BSEE; (2) Will this information be processed and used in a timely manner; (3) Is the estimate of burden accurate; (4) How might BSEE enhance the quality, utility, and clarity of the information to be collected; and (5) How might BSEE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying

information from public review, we cannot guarantee that we will be able to do so.

Abstract: The regulations at 30 CFR part 250, subpart O, concern well control and production safety training and are the subject of this collection. This request also covers any related Notices to Lessees and Operators (NTLs) that BSEE issues to clarify, supplement, or provide additional guidance on some aspects of our regulations.

The BSEE will use the information collected under subpart O regulations to ensure that workers in the OCS are properly trained with the necessary skills to perform their jobs in a safe and pollution-free manner.

In some instances, we may conduct oral interviews of offshore employees to evaluate the effectiveness of a company's training program. The oral interviews are used to gauge how effectively the companies are implementing their own training program.

Title of Collection: 30 CFR 250, Subpart O, *Well Control and Production Safety Training.*

OMB Control Number: 1014–0008.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Potential respondents comprise Federal OCS oil, gas, and sulfur lessees/operators and holders of pipeline rights-of-way.

Total Estimated Number of Annual Respondents: Varies, not all of the potential respondents will submit information in any given year and some may submit multiple times.

Total Estimated Number of Annual Responses: 6.

Estimated Completion Time per Response: Varies from 1 hour to 105 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 202.

Respondent's Obligation: Most responses are mandatory, while others are required to obtain or retain benefits.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: We have not identified any non-hour cost burdens associated with this collection of information.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Dated: March 5, 2018.

Doug Morris,

Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2018–07976 Filed 4–16–18; 8:45 am]

BILLING CODE 4310–VH–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. U.S.-Korea FTA–103–031]

U.S.-Korea FTA: Advice on Modifications to Duty Rates for Certain Motor Vehicles

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and notice of opportunity to provide written comments.

SUMMARY: Following receipt on April 6, 2018, of a request from the U.S. Trade Representative (USTR), the Commission instituted investigation No. U.S.-Korea FTA–103–031, *U.S.-Korea FTA: Advice on Modifications to Duty Rates for Certain Motor Vehicles,* for the purpose of providing advice on the probable economic effect of modifications to the United States-Korea Free Trade Agreement regarding the staging of duty treatment for certain motor vehicles.

DATES: May 1, 2018: Deadline for filing written submissions.

June 1, 2018: Transmittal of Commission report to USTR.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street SW, Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW, Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://www.usitc.gov/secretary/edis.htm.*

FOR FURTHER INFORMATION CONTACT: Project Leader Jeff Horowitz (202–205–2750 or *jeffrey.horowitz@usitc.gov*) or Deputy Project Leader Mitch Semanik (202–205–2034 or *mitchell.semanik@usitc.gov*) for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). 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.

Background: In his request letter (received April 6, 2018), the USTR stated that U.S. negotiators have recently reached an agreement in principle with representatives of the government of Korea on modifications to the FTA regarding the staging of duty treatment for certain motor vehicles. The USTR noted that section 201(b)(2) of the United States—Korea Free Trade Agreement Implementation Act (the Act) authorizes the President, subject to the consultation and layover requirements of section 104 of the Act, to proclaim such tariff modifications as the President determines to be necessary or appropriate to maintain the general level of reciprocal and mutually advantageous concessions with respect to Korea provided for by the FTA. He noted that one of the requirements set out in section 104 of the Act is that the President obtain advice regarding the proposed action from the U.S. International Trade Commission.

In the request letter, the USTR asked that the Commission provide advice on the probable economic effect of the modifications on U.S. trade under the FTA and on domestic producers of the affected articles. He asked that the Commission provide its advice at the earliest possible date but no later than eight weeks from receipt of the request. He also asked that the Commission issue, as soon as possible thereafter, a public version of its report with any confidential business information deleted.

The products identified in the proposal are motor vehicles for the transport of goods provided for in subheadings 8704.21.00, 8704.22.50, 8704.23.00, 8704.31.00, 8704.32.00, and 8704.90.00 of the U.S. Harmonized Tariff Schedule. The request letter and the proposed modification are available on the Commission's website at *http://www.usitc.gov/research_and_analysis/what_we_are_working_on.htm.* As requested, the Commission will provide its advice to USTR by June 1, 2018.

Written Submissions: No public hearing is planned. However, interested parties are invited to file written submissions. All written submissions should be addressed to the Secretary, and should be received no later than

5:15 p.m., May 1, 2018. All written submissions must conform with the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 and the Commission's Handbook on Filing Procedures require that interested parties file documents electronically on or before the filing deadline and submit eight (8) true paper copies by 12:00 p.m. eastern time on the next business day. In the event that confidential treatment of a document is requested, interested parties must file, at the same time as the eight paper copies, at least four (4) additional true paper copies in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202–205–1802).

Confidential Business Information: Any submissions that contain confidential business information must also conform with the requirements of section 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the confidential business information is clearly identified by means of brackets. All written submissions, except for those containing CBI, will be made available for inspection by interested parties.

The Commission may include some or all of the confidential business information submitted in the course of this investigation in the report it sends to the USTR. Additionally, all information, including CBI, submitted in this investigation 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 for cybersecurity purposes. The Commission will not otherwise disclose any confidential business information in a manner that would reveal the operations of the firm supplying the information.

Summaries Of Written Submissions: The Commission intends to publish summaries of the positions of interested persons in an appendix to its report. Persons wishing to have a summary of their position included in the appendix should include a summary with their written submission. The summary may not exceed 500 words, should be in MSWord format or a format that can be easily converted to MSWord, and should not include any CBI. The summary will be included in the report as provided if it meets these requirements and is germane to the subject matter of the investigation. In the appendix, the Commission will identify the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the full written submission can be found.

By order of the Commission.

Issued: April 12, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–08015 Filed 4–16–18; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Clinical Supplies Management Holdings, Inc.

ACTION: Notice of application.

DATES: Registered bulk importers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before May 17, 2018. Such persons may also file a written request for a hearing on the application on or before May 17, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417, (January 25, 2007)

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on March 14, 2018, Clinical Supplies Management Holdings, Inc., 342 42nd Street South, Fargo, ND 58103 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to import analytical reference standards for distribution to its customers for research and analytical purposes. Placement of these drug codes onto the company's registration does not translate into automatic approval of subsequent permit applications to import controlled substances. Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: April 10, 2018.

Susan A. Gibson,

Deputy Assistant Administrator.

[FR Doc. 2018–07978 Filed 4–16–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0015]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Application for Registration, Application for Registration Renewal; DEA Forms 363, 363a

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day Notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register**, on February 21, 2018, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until May 17, 2018.

FOR FURTHER INFORMATION CONTACT: If you have comments 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 Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812 or sent to *OIRA_submission@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Application for Registration, Application for Registration Renewal.

3. The agency form number, if any, and the applicable component of the Department sponsoring the collection: The form numbers are DEA Forms 363, 363a. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public: Business or other for-profit.

Affected public (Other): Not-for-profit institutions, Federal, State, local, and tribal governments.

Abstract: The Controlled Substances Act requires practitioners who dispense narcotic drugs to individuals for maintenance or detoxification treatment to register annually with DEA.[1] 21 U.S.C. 822, 823; 21 CFR 1301.11 and 1301.13. Registration is a necessary control measure and helps to prevent diversion by ensuring the closed system of distribution of controlled substances can be monitored by DEA and the businesses and individuals handling controlled substances are qualified to do so and are accountable.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* DEA Form 363 is submitted on an as needed basis by persons seeking to become registered; DEA Form 363a is submitted on an annual basis thereafter to renew existing registrations. The below table presents information regarding the number of respondents, responses and associated burden hours.

	Number of annual respondents	Average time per response	Total annual hours
DEA Form 363 (paper)	15	0.30 hours (18 minutes)	5
DEA Form 363 (online)	223	0.13 hours (8 minutes)	30
DEA Form 363a (paper)	51	0.22 hours (13 minutes)	11
DEA Form 363a (online)	1,437	0.10 hours (6 minutes)	144
Total	1,726		189

Figures are rounded.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates that this collection takes 189 annual burden hours.

If additional information is required please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: April 11, 2018.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2018–07904 Filed 4–16–18; 8:45 am]

BILLING CODE 4410–09–P

[1] This registration requirement is waived for certain practitioners under specified circumstances. See 21 U.S.C. 823(g)(2).

DEPARTMENT OF JUSTICE

Civil Rights Division

[OMB Number 1190–0009]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change of a Currently-Approved Collection, Title II of the Americans With Disabilities Act of 1990/Section 504 of the Rehabilitation Act of 1973 Discrimination Complaint Form

AGENCY: Disability Rights Section, Civil Rights Division, U.S. Department of Justice.

ACTION: 60 Day notice.

SUMMARY: The Department of Justice, Civil Rights Division, Disability Rights Section, is 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 Department of Justice encourages public comment and will accept input until June 18, 2018.

Comments received after the close of the comment period are disfavored and will be marked ''late.'' The Department is not required to consider late comments.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Rebecca Bond, Chief, U.S. Department of Justice, Civil Rights Division, Disability Rights Section, NYA, 950 Pennsylvania Avenue NW, Washington, DC 20530, *DRS.PRA@usdoj.gov,* or by telephone at (800) 514–0301 (Voice) or (800) 514–0383 (TTY) (the Division's ADA Information Line). All submissions should reference the eight-digit OMB number for the collection or the title of the collection.

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 collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so, how, the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses).

Overview of This Information Collection

1. *Type of information collection:* Extension of Currently Approved Collection.
2. *The Title of the Form/Collection:* Title II of the Americans with Disabilities Act/Section 504 of the Rehabilitation Act of 1973 Discrimination Complaint Form.
3. *The agency form number and applicable component of the Department sponsoring the collection:* The document has no agency form number. The applicable component within the Department of Justice is the Disability Rights Section, Civil Rights Division.
4. *Affected public who will be asked to respond, as well as a brief abstract: Primary:* Individuals alleging discrimination by public entities based on disability. Under title II of the Americans with Disabilities Act, an individual who believes that he or she has been subjected to discrimination on the basis of disability by a public entity may, by himself or herself or by an authorized representative, file a complaint. The Department of Justice must address the complaint or refer the complaint to the appropriate Federal agency. Any Federal agency that receives a complaint of discrimination on the basis of disability by a public entity must review the complaint to determine whether it has jurisdiction under Section 504. If the agency does not have jurisdiction under Section 504, it must determine whether it is the designated agency responsible for complaints filed against that public entity under title II of the ADA. If the agency does not have jurisdiction under section 504 and is not the designated agency under title II of the ADA, it must refer the complaint to the Department of Justice.
5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 11,192 respondents per year at 0.75 hours per complaint form.
6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 8,394 hours, which is equal to 11,192 respondents * .75 hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: April 12, 2018.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2018–07979 Filed 4–16–18; 8:45 am]

BILLING CODE 4410–13–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0012]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Application for Registration, Application for Registration Renewal, Affidavit for Chain Renewal; DEA Forms 225, 225a and 225b

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register**, on February 21, 2018, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until May 17, 2018.

FOR FURTHER INFORMATION CONTACT: If you have comments 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 Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia

22152; Telephone: (202) 598–6812 or sent to *OIRA_submission@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Application for Registration, Application for Registration Renewal, Affidavit for Chain Renewal.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form numbers are DEA Forms 225, 225a, and 225b. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public: Business or other for-profit.

Affected public (Other): Not-for-profit institutions, Federal, State, local, and tribal governments.

Abstract: The Controlled Substances Act requires all businesses and individuals who manufacture, distribute, import, export, and conduct research and laboratory analysis with controlled substances to register with DEA. 21 U.S.C. 822, 21 CFR 1301.11 and 1301.13. Registration is a necessary control measure and helps to prevent diversion by ensuring the closed system of distribution of controlled substances can be monitored by DEA and the businesses and individuals handling controlled substances are qualified to do so and are accountable.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The below table presents information regarding the number of respondents, responses and associated burden hours.

	Number of annual respondents	Average time per response	Total annual hours
DEA–225 (paper)	308	0.33 hours (20 minutes)	103
DEA–225 (online)	1,993	0.17 hours (10 minutes)	332
DEA–225a (paper)	366	0.25 hours (15 minutes)	92
DEA–225a (online)	13,248	0.12 hours (7 minutes)	1,546
DEA–225b (chain renewal)*	4	1 hour	4
Total	15,919		2,076

* In total, 4 chains represent 82 individual registrant locations. Figures are rounded.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates that this collection takes 2,076 annual burden hours.

If additional information is required please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: April 11, 2018.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2018–07905 Filed 4–16–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Parole Commission

Sunshine Act Meeting

TIME AND DATE: 11:00 a.m. Tuesday, April 24, 2018

PLACE: U.S. Parole Commission, 90 K Street NE, 3rd Floor, Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: Approval of February 13, 2018 minutes; Reports from the Vice Chairman, Commissioners and Senior Staff.

CONTACT PERSON FOR MORE INFORMATION: Jacqueline Graham, Staff Assistant to the Chairman, U.S. Parole Commission, 90 K Street NE, 3rd Floor, Washington, DC 20530, (202) 346–7010.

Dated: April 13, 2018.

J. Patricia Wilson Smoot,

Chairperson, U.S. Parole Commission.

[FR Doc. 2018–08143 Filed 4–13–18; 4:15 pm]

BILLING CODE 4410–31–P

DEPARTMENT OF JUSTICE

Parole Commission

Sunshine Act Meeting

TIME AND DATE: 12:00 a.m., Tuesday, April 24, 2018.

PLACE: U.S. Parole Commission, 90 K Street NE, 3rd Floor, Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Determination on ONE original jurisdiction cases.

CONTACT PERSON FOR MORE INFORMATION: Jacqueline Graham, Staff Assistant to the Chairman, U.S. Parole Commission, 90 K Street NE, 3rd Floor, Washington, DC. 20530, (202) 346–7001.

Dated: April 13, 2018.

J. Patricia Wilson Smoot,

Chairperson, U.S. Parole Commission.

[FR Doc. 2018–08144 Filed 4–13–18; 4:15 pm]

BILLING CODE 4410–31–P

NATIONAL SCIENCE FOUNDATION

Notice of Intent To Seek Approval To Renew an Information Collection

AGENCY: National Science Foundation.

ACTION: Notice and request for comments.

SUMMARY: Under the Paperwork Reduction Act of 1995, and as part of its continuing effort to reduce paperwork and respondent burden, the National Science Foundation (NSF) is inviting the general public or other Federal agencies to comment on this proposed continuing information collection. NSF will publish periodic summaries of the proposed projects.

DATES: Written comments on this notice must be received by June 18, 2018, to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

SUPPLEMENTARY INFORMATION:

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Foundation, including whether the information will have practical utility; (b) the accuracy of the Foundation'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 collection techniques or other forms of information technology.

Title of Collection: Grantee Reporting Requirements for the Engineering Research Centers (ERCs).

OMB Number: 3145–0220.

Expiration Date of Approval: June 30, 2018.

Type of Request: Intent to seek approval to renew an information collection.

Abstract

Proposed Project: The Engineering Research Centers (ERC) program supports an integrated, interdisciplinary research environment to advance fundamental engineering knowledge and engineered systems; educate a globally competitive and diverse engineering workforce from K–12 on; and join academe and industry in partnership to achieve these goals. ERCs conduct world-class research through partnerships of academic institutions, national laboratories, industrial organizations, and/or other public/private entities. New knowledge thus created is meaningfully linked to society.

ERCs conduct world-class research with an engineered systems perspective that integrates materials, devices, processes, components, control algorithms and/or other enabling elements to perform a well-defined function. These systems provide a unique academic research and education experience that involves integrative complexity and technological realization. The complexity of the systems perspective includes the factors associated with its use in industry, society/environment, or the human body.

ERCs enable and foster excellent education, integrate research and education, speed knowledge/technology transfer through partnerships between academe and industry, and prepare a more competitive future workforce. ERCs capitalize on diversity through participation in center activities and demonstrate leadership in the involvement of groups underrepresented in science and engineering.

Centers are required to submit annual reports on progress and plans, which will be used as a basis for performance review and determining the level of continued funding. To support this review and the management of a Center, ERCs also are required to submit management and performance indicators annually to NSF via a data collection website that is managed by a technical assistance contractor. These indicators are both quantitative and descriptive and may include, for example, the characteristics of center personnel and students; sources of cash and in-kind support; expenditures by operational component; characteristics of industrial and/or other sector participation; research activities; education activities; knowledge transfer activities; patents, licenses; publications; degrees granted to students involved in Center activities; descriptions of significant advances and other outcomes of the ERC effort. Such reporting requirements will be included in the cooperative agreement which is binding between the academic institution and the NSF.

Each Center's annual report will address the following categories of activities: (1) Vision and impact, (2) strategic plan, (3) research program, (4) innovation ecosystem and industrial collaboration, (5) education, (6) infrastructure (leadership, management, facilities, diversity) and (7) budget issues.

For each of the categories the report will describe overall objectives for the year, progress toward center goals, problems the Center has encountered in making progress towards goals and how they were overcome, plans for the future and anticipated research and other barriers to overcome in the following year, and specific outputs and outcomes.

Use of the Information: The data collected will be used for NSF internal reports, historical data, performance review by peer site visit teams, program level studies and evaluations, and for securing future funding for continued ERC program maintenance and growth.

Estimate of Burden: 150 hours per center for 17 centers for a total of 2,550 hours.

Respondents: Academic institutions.

Estimated Number of Responses per Report: One from each of the 17 ERCs.

Dated: April 12, 2018.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2018–07983 Filed 4–16–18; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Reliability and Probabilistic Risk Assessment; Notice of Meeting

The ACRS Subcommittee on Reliability and Probabilistic Risk Assessment will hold a meeting on May 2, 2018 at 11545 Rockville Pike, Room T–2B1, Rockville, Maryland 20852.

The meeting will be open to public attendance with the exception of portions that will be closed to protect information that is proprietary pursuant to 5 U.S.C. 552b(c)(4). The agenda for the subject meeting shall be as follows:

Wednesday, May 2, 2018—8:30 a.m. Until 5:00 p.m.

The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons on the progress of the Level 3

Probabilistic Risk Assessment Project. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Christiana Lui (Telephone 301–415–2492 or Email *Christiana.Lui@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 4, 2017 (82 FR 46312).

Detailed meeting agendas and meeting transcripts are available on the NRC website at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the website cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, Maryland 20852. After registering with Security, please contact Mr. Theron Brown (Telephone 301–415–6702) to be escorted to the meeting room.

Dated: April 11, 2018.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2018–07938 Filed 4–16–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Planning and Procedures; Notice of Meeting

The ACRS Subcommittee on Planning and Procedures will hold a meeting on May 2, 2018, 11545 Rockville Pike, Room T–2B3, Rockville, Maryland 20852.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, May 2, 2018—12:00 p.m. until 1:00 p.m.

The Subcommittee will discuss proposed ACRS activities and related matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Quynh Nguyen (Telephone 301–415–5844 or Email: *Quynh.Nguyen@nrc.gov*) five days prior to the meeting, if possible, so that arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 4, 2017 (82 FR 46312).

Information regarding changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the DFO if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, Maryland 20852. After registering with Security, please contact Mr. Theron Brown at 301–415–6702 to be escorted to the meeting room.

Dated: April 11, 2018.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2018–07937 Filed 4–16–18; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:30 p.m. on Thursday, April 19, 2018.

PLACE: Closed Commission Hearing, Room 10800.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

Commissioner Jackson, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matters of the closed meeting will be:

Institution of injunctive actions;

Institution and settlement of administrative proceedings;

Litigation matter; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: April 12, 2018.

Brent J. Fields,

Secretary.

[FR Doc. 2018–08083 Filed 4–13–18; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83033; File No. SR–Phlx–2018–14)

Self-Regulatory Organizations; Nasdaq PHLX LLC; Order Approving a Proposed Rule Change, as Modified by Amendment Nos. 1, 2, and 3, To Adopt Protections for Butterfly Spreads and Box Spreads

April 11, 2018.

I. Introduction

On February 9, 2018, Nasdaq PHLX LLC (''Phlx'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Phlx Rule 1098, ''Complex Orders on the System,'' to adopt protections for Complex Orders that are box spreads or butterfly spreads.[3] On February 21, 2018, the Exchange filed Amendment No. 1 to the proposed rule change, which superseded the original filing in its entirety. The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on March 1, 2018.[4] On April 9, 2018, the Exchange filed Amendment No. 2 to the proposal. On April 10, 2018, the Exchange filed Amendment No. 3 to the proposal, which superseded Amendment No. 2 in its entirety.[5] The Commission received no comments regarding the proposed rule change. This order approves the proposed rule change, as modified by Amendment Nos. 1, 2, and 3.

II. Description of the Proposed Rule Change, as Modified by Amendment Nos. 1, 2, and 3

As described more fully in the Notice, the Exchange proposes to amend Phlx Rule 1098 to adopt protections that will prevent the execution of a butterfly spread [6] or a box spread [7] at a price outside of specified minimum and maximum values (the ''Butterfly Spread Protection'' and the ''Box Spread Protection,'' respectively).[8] Under the Butterfly Spread Protection, a butterfly spread that is priced higher than the Maximum Value [9] or lower than the Minimum Value [10] will be cancelled. A butterfly spread entered as a market order will be accepted but will be restricted from trading at a price that is higher than the Maximum Value or lower than the Minimum Value. [11] Similarly, under the Box Spread Protection, a box spread that is priced higher than the Maximum Value [12] or lower than the Minimum Value [13] will be cancelled. A box spread entered as a market order will be accepted but will be restricted from trading at a price that is higher than the Maximum Value or lower than the Minimum Value.[14] The Butterfly Spread Protection and the Box Spread Protection apply to orders being auctioned and to auction responses, and they apply throughout the trading day, including during the pre-market, the opening process, and trading halts.[15]

The Phlx states that the proposal is responsive to member input and will provide members with additional functionality that will assist them in managing risk.[16] In addition, the Phlx states that the buffer allowance from the minimum and maximum values permitted for the execution of butterfly and box spreads will provide market participants with flexibility to manage their business.[17] The Phlx notes that it currently offers similar order protection features for Complex Orders to avoid erroneous trades, including the Strategy Price Protection and the Acceptable Complex Execution (''ACE'') Parameter.[18]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[19] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[20] which requires, among other things, that the rules of a national securities exchange be

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] For purposes of the electronic trading of Complex Orders, a ''Complex Order'' is an order involving the simultaneous purchase and/or sale of two or more different options series in the same underlying security, priced as a net debit or credit based on the relative prices of the individual components, for the same account, for the purpose of executing a particular investment strategy. *See* Phlx Rule 1098(a)(i).

[4] *See* Securities Exchange Act Release No. 82766 (February 23, 2018), 83 FR 8914 (March 1, 2018) (''Notice'').

[5] In Amendment No. 3, the Phlx revised the proposal to (1) replace references in proposed Phlx Rule 1098(i)(i) to ''Complex Order'' with ''Butterfly Spread,'' and to ''Complex Market Order'' with ''Butterfly Spread entered as a Market Order;'' (2) revise proposed Phlx Rule 1098(i)(i)(a) to indicate that the Initial Maximum Value is the distance between the strike price of the leg with the mid-point and either of the outer leg strike prices; (3) replace references in proposed Phlx Rule 1098(j)(i) to ''Complex Order'' with ''Box Spread'' and to ''Complex Market Order'' with ''Box Spread entered as a Market Order;'' (4) amend proposed Phlx Rules 1098(i)(i) and (j)(i) to refer to ''an order being auctioned,'' rather than an ''auction;'' and (5) delete the reference to ''spread'' in proposed Phlx Rule 1098(j)(i)(b). Because Amendment No. 3 makes only clarifying and technical changes, and does not present unique or novel regulatory issues, it is not subject to notice and comment.

[6] A butterfly spread is a three legged Complex Order with the following: (1) Two legs to buy (sell) the same number of calls (puts); (2) one leg to sell (buy) twice the number of calls (puts) with a strike price at mid-point of the two legs to buy (sell); (3) all legs have the same expiration; and (4) each leg strike price is equidistant from the next sequential strike price. *See* proposed Phlx Rule 1098(i).

[7] A box spread is a four legged Complex Order with the following: (1) One pair of legs with the same strike price with one leg to buy a call (put) and one leg to sell a put (call); (2) a second pair of legs with a different strike price from the pair described in (1) with one leg to sell a call (put) and one leg to buy a put (call); (3) all legs have the same expiration; and (4) all legs have equal volume. *See* proposed Phlx Rule 1098(j).

[8] *See* Notice, 83 FR at 8915.

[9] For a butterfly spread, the Maximum Value is calculated by adding the Initial Maximum Value (the distance between strike price of the leg with the mid-point strike and either of the outer leg strike prices) and the Maximum Value Buffer. The Maximum Value Buffer is the lesser of a configurable absolute dollar value or percentage of the Initial Maximum Value set by the Exchange and announced via a notice to members. *See* proposed Phlx Rule 1098(i)(i)(a).

[10] For a butterfly spread, the Minimum Value is calculated by subtracting the Minimum Value Buffer (a configurable absolute dollar value set by the Exchange and announced via a notice to members) from the Initial Minimum Value of zero. *See* proposed Phlx Rule 1098(i)(i)(b). The Phlx notes that the Minimum Value could be less than zero. *See* Notice, 83 FR at 8915. The Phlx states that a market participant seeking to trade out of a position at intrinsic value might not find a contra-side willing to trade without a premium. The Phlx notes that an incremental allowance outside of the minimum/maximum value would allow for a small premium to offset commissions associated with trading and could incentivize participants to take the other side of a spread trading at intrinsic value. The Phlx further notes that a participant might find it financially beneficial to pay a small premium to close out its position rather than carry the position to expiration and take delivery. *See id.*

[11] *See* proposed Phlx Rule 1098(i)(i).

[12] For a box spread, the Maximum Value is calculated by adding the Initial Maximum Value (the distance between the strike prices of each pair of leg strike prices) and the Maximum Value Buffer. The Maximum Value Buffer is the lesser of a configurable absolute dollar value or percentage of the Initial Maximum value set by the Exchange and announced via a notice to members. *See* proposed Phlx Rule 1098(j)(i)(a).

[13] For a box spread, the Minimum Value is calculated by subtracting the Minimum Value Buffer (a configurable absolute dollar value set by the Exchange and announced via a notice to members) from the Initial Minimum Value of zero. *See* proposed Phlx Rule 1098(j)(i)(b).

[14] *See* proposed Phlx Rule 1098(j)(i).

[15] *See* proposed Phlx Rules 1098(i)(i) and (ii), and 1098(j)(i) and (ii).

[16] *See* Notice, 83 FR at 8916.

[17] *See id.* at 8917.

[18] *See id.* at 8915. *See also* Phlx Rules 1098(g) (Strategy Price Protection) and 1098(h)(i) (ACE Parameter).

[19] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[20] 15 U.S.C. 78f(b)(5).

designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Commission believes that the Butterfly Spread Protection and the Box Spread Protection will help market participants mitigate risk by preventing the execution of butterfly and box spreads at prices that are outside of specified minimum and maximum values. The Commission notes that the Phlx has indicated that the protections are responsive to input from Phlx members.[21] In addition, the Commission notes that another options exchange has adopted similar price protections.[22]

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[23] that the proposed rule change (SR–Phlx–2018–14), as modified by Amendment Nos. 1, 2, and 3, is approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–07932 Filed 4–16–18; 8:45 am]

BILLING CODE 8011–01–P

[21] *See* Notice, 83 FR at 8916.

[22] *See* CBOE Rule 6.53C, Interpretation and Policy .08(g).

[23] 15 U.S.C. 78s(b)(2).

[24] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, Washington, DC 20549–2736

Extension:

Rule 15g–4, SEC File No. 270–347, OMB Control No. 3235–0393

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 15g–4—Disclosure of compensation to brokers or dealers (17 CRF 240.15g–4) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 15g–4 requires brokers and dealers effecting transactions in penny stocks for or with customers to disclose the amount of compensation received by the broker-dealer in connection with the transaction. The purpose of the rule is to increase the level of disclosure to investors concerning penny stocks generally and specific penny stock transactions.

The Commission estimates that approximately 195 broker-dealers will spend an average of 87 hours annually to comply with this rule. Thus, the total compliance burden is approximately 16,965 burden-hours per year.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Pamela Dyson, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE, Washington, DC 20549 or send an email to *PRA_Mailbox@sec.gov.*

Dated: April 11, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–07961 Filed 4–16–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 6e–2 and Form N–6EI–1, SEC File No. 270–177, OMB Control No. 3235–0177

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 6e–2 (17 CFR 270.6e–2) under the Investment Company Act of 1940 (''Act'') (15 U.S.C. 80a) is an exemptive rule that provides separate accounts formed by life insurance companies to fund certain variable life insurance products, exemptions from certain provisions of the Act, subject to conditions set forth in the rule.

Rule 6e–2 provides a separate account with an exemption from the registration provisions of section 8(a) of the Act if the account files with the Commission Form N–6EI–1 (17 CFR 274.301), a notification of claim of exemption.

The rule also exempts a separate account from a number of other sections of the Act, provided that the separate account makes certain disclosure in its registration statements (in the case of those separate account that elect to register), reports to contract holders, proxy solicitations, and submissions to state regulatory authorities, as prescribed by the rule.

Since 2008, there have been no filings of Form N–6EI–1 by separate accounts. Therefore, there has been no cost or burden to the industry since that time. The Commission requests authorization to maintain an inventory of one burden hour for administrative purposes.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following website, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: April 11, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–07960 Filed 4–16–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83032; File No. SR–NYSEArca–2018–20]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Equities Fees and Charges

April 11, 2018.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder, [3] notice is hereby given that, on March 30, 2018, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Fees and Charges (''Fee Schedule'') to (i) revise the requirements to qualify for the Step-Up Tier; (ii) adopt a new pricing tier, BBO Setter Tier; (iii) delete the Tape A and Tape C Tier; (iv) eliminate the credits associated with indications of interest (''IOIs''); (v) delete obsolete language related to an Exchange Traded Product (''ETP'') Incentive Program; and (vi) modify the credit the Exchange provides for orders with the Self Trade Prevention (''STP'') Cancel Both (''STPC'') and STP Decrement and Cancel (''STPD'') Modifiers. The Exchange proposes to implement the fee changes effective April 2, 2018. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule, as described below, to (i) revise the requirements for the Step-Up Tier; (ii) adopt a new pricing tier, BBO Setter Tier; (iii) delete the Tape A and Tape C Tier; (iv) eliminate the credits associated with IOIs; (v) delete obsolete language related to an ETP Incentive Program; and (vi) modify the credit the Exchange provides for orders with the STPC and STPD Modifiers. The Exchange proposes to implement the fee changes on April 2, 2018.

Step-Up Tier

In September 2016, the Exchange filed a proposed rule change to adopt a new Step-Up pricing tier that was intended to incentivize ETP Holders and Market Makers to increase order flow and provide additional liquidity.[4] In September 2017, the Exchange filed a proposed rule change to adopt a second way by which an ETP Holder or Market Maker could qualify for the Step-Up Tier.[5] Currently, to qualify for the Step-Up Tier, ETP Holders and Market Makers, on a daily basis, measured monthly must: (i) directly execute providing average daily volume that is an increase of no less than 0.15% of US CADV [6] for that month over the ETP Holder's or Market Maker's providing average daily volume in July 2016, and (ii) sets a new NYSE Arca Best Bid or Offer with at least 25% in each of the ETP Holder's or Market Maker's Tape A, Tape B and Tape C providing ADV. ETP Holders and Market Makers can alternatively qualify for the Step-Up Tier if such ETP Holder or Market Maker, on a daily basis, measured monthly: (i) Directly execute providing average daily volume that is an increase of no less than 0.15% of US CADV for that month over the ETP Holder's or Market Maker's providing average daily volume in July 2016, and (ii) sets a new NYSE Arca Best Bid or Offer with at least 20% in the ETP Holder's or Market Maker's Tape A providing ADV, at least 25% in the ETP Holder's or Market Maker's Tape B providing ADV, and at least 30% in the ETP Holder's or Market Maker's Tape C providing ADV, and (iii) directly execute taking average daily volume of at least 15 million shares. ETP Holders and Market Makers that qualify for the Step-Up Tier receive a credit of $0.0029 per share for orders that provide liquidity to the Book in Tape A and Tape C Securities and $0.0028 per share for orders that provide liquidity to the Book in Tape B Securities.

The Step-Up Tier has not encouraged ETP Holders and Market Makers to increase their activity to qualify for this pricing tier as significantly as the Exchange had anticipated that it would. As a result, the Exchange proposes to revise the current requirements to qualify for the Step-Up Tier. As proposed, ETP Holders and Market Makers would qualify for the Step-Up Tier if they directly execute providing average daily volume per month of 0.50% or more but less than 0.70% of the US CADV, and directly execute providing ADV that is an increase of no less than 0.10% of US CADV for that month over the ETP Holder's or Market Maker's providing ADV in Q1 2018. ETP Holders and Market Makers that qualify for the Step-Up Tier would receive a credit of $0.0030 per share for orders that provide displayed liquidity to the Book in Tape A Securities, $0.0023 per share for orders that provide displayed liquidity to the Book in Tape B Securities, and $0.0031 per share for orders that provide displayed liquidity in Tape C Securities.

The goal of the Step-Up Tier remains the same, *i.e.,* to incentivize ETP Holders and Market Makers to increase the orders sent directly to NYSE Arca and therefore provide liquidity that supports the quality of price discovery

[4] *See* Securities Exchange Act Release No. 78892 (September 21, 2016), 81 FR 66315 (September 27, 2016) (SR–NYSEArca–2016–128).

[5] *See* Securities Exchange Act Release No. 81601 (September 13, 2017), 82 FR 43633 (September 18, 2017) (SR–NYSEArca–2017–104).

[6] US CADV means United States Consolidated Average Daily Volume for transactions reported to the Consolidated Tape, excluding odd lots through January 31, 2014 (except for purposes of Lead Market Maker pricing), and excludes volume on days when the market closes early and on the date of the annual reconstitution of the Russell Investments Indexes. Transactions that are not reported to the Consolidated Tape are not included in US CADV.

and promotes market transparency.[7] The Exchange believes that the proposed new qualifying requirement for the Step-Up Tier will provide an incentive for ETP Holders or Market Makers that are active traders on the Exchange to increase the orders sent to the Exchange that would provide liquidity.

BBO Setter Tier

The Exchange proposes a new pricing tier—BBO Setter Tier—for securities with a per share price of $1.00 or above.

As proposed, a new BBO Setter Tier credit of $0.0004 per share for orders that set a new NYSE Arca BBO in Tape A and Tape C Securities and $0.0002 per share for orders that set a new NYSE Arca BBO in Tape B Securities would apply to ETP Holders and Market Makers that directly execute providing ADV per month of 0.70% or more of the US CADV, and provided that an ETP ID[8] associated with an ETP Holder or Market Maker, on a daily basis, measured monthly (1) Directly executes providing ADV of at least 0.20% of US CADV, (2) sets a new NYSE Arca BBO with at least 0.10% of US CADV; and (3) sets a new NYSE Arca BBO of at least 40% of that ETP Holder's or Market Maker's ETP ID providing ADV. The proposed credit would be in addition to the ETP Holder's or Market Maker's Tiered or Basic Rate credit(s), and for Tape B and Tape C Securities, the proposed credit would be in addition to any capped credit.[9]

For example, assume an ETP Holder or Market Maker qualifies for the Tape C Tier 1 credit of $0.0032 per share for orders that provide liquidity to the Book. Assume further that the same ETP Holder or Market Maker also qualifies for the Tape C Tier 2 incremental credit of $0.0002 per share. Pursuant to the Tape C Tier 2 pricing tier, the ETP Holder or Market Maker's credit cannot exceed $0.0033 per share. In this example, the ETP Holder or Market Maker's credit would be capped at $0.0033 per share. Assume further that the ETP Holder or Market Maker has an ETP ID that qualifies for the proposed BBO Setter Tier, which would provide an additional credit of $0.0004 per share to the qualifying ETP ID, and combined with the ETP Holder or Market Maker's credit of $0.0033 per share, the ETP Holder or Market Maker in this example would receive a total credit of $0.0037 per share for orders that set a new NYSE Arca BBO. The ETP ID's orders that do not set a new NYSE Arca BBO would not receive the proposed BBO Setter Tier credit.

Tape A and Tape C Tier

In July 2017, the Exchange filed a proposed rule change to adopt a new pricing tier—Tape A and Tape C Tier—as an incentive for ETP Holders and Market Makers to provide liquidity in Tape A and Tape C Securities.[10] The Tape A and Tape C Tier has not encouraged ETP Holders and Market Makers to increase their activity to qualify for this pricing tier as significantly as the Exchange had anticipated they would. As a result, the Exchange proposes to remove this pricing tier from the Fee Schedule.

IOI Credit

In August 2008, the Exchange filed a proposed rule change to adopt credits that apply to indications of interest (''IOIs'') submitted by ETP Holders that result in routed and executed orders.[11] IOIs are non-displayed indications of symbol, size and side, which do not interact with the NYSE Arca Book. At their discretion, participating ETP Holders may send an IOI to the Exchange, which in turn considers the IOI when determining potential destinations for outbound routes. The purpose for adopting IOI Credits was to incentivize ETP Holders to participate in the Exchange's IOI program and provide additional liquidity to the marketplace. The IOI Credits have not incentivized ETP Holders to participate in the IOI program as anticipated by the Exchange. As a result, the Exchange proposes to eliminate the credits associated with IOIs by deleting IOI Credit Tier 2 and IOI Credit Tier 3 entirely and renaming IOI Credit Tier 1 as IOI Credit. With this proposed rule change, the Exchange would no longer provide credits associated with IOIs. The Exchange proposes to reflect the elimination of the credits by adopting rule text on the Fee Schedule that would replace the current tiered credits with ''No Credit.''

ETP Incentive Program

The Exchange proposes to amend the Fee Schedule to reflect the termination of a pilot program designed to incentivize quoting and trading in Exchange Traded Products (''ETPs'') and to add competition among existing qualified Market Makers[12] (''ETP Incentive Program''). The ETP Incentive Program was also designed to enhance the market quality for ETPs by incentivizing Market Makers to take Lead Market Maker (''LMM'')[13] assignments in certain lower-volume ETPs by offering an alternative fee structure for such LMMs.[14] The ETP Incentive Program was established in 2013.[15] The Exchange subsequently filed to extend it in 2014,[16] in 2015,[17] and finally in 2016.[18] However, the Exchange did not extend the program and it expired on July 31, 2017. The Exchange proposes to remove reference to the ETP Incentive Program from the Fee Schedule.

STP Modifier

The Exchange currently provides STP Modifiers that allow ETP Holders entering orders to elect to prevent those orders from executing against other orders entered on the Exchange by the

[7] *See supra,* note 5, at 43634.

[8] ETP Holders enter orders and order instructions by using communication protocols that map to the order types and modifiers described in Exchange rules. The Exchange makes available ports that communicate with the Exchange using Pillar phase I protocols and Pillar phase II protocols. For purposes of the BBO Setter Tier, references to ETP ID means an ETP ID when using Pillar phase I protocols to communicate with the NYSE Arca Marketplace or an MPID when using Pillar phase II protocols to communicate with the NYSE Arca Marketplace.

[9] The Exchange does not have any capped credits for trading in Tape A Securities.

[10] *See* Securities Exchange Act Release No. 81134 (July 12, 2017), 82 FR 32911 (July 18, 2017) (SR–NYSEArca–2017–72).

[11] *See* Securities Exchange Act Release Nos. 58397 (August 20, 2008), 73 FR 50389 (August 26, 2008) (SR–NYSEArca–2008–83); 59521 (March 5, 2009), 74 FR 10640 (March 11, 2009) (SR–NYSEArca–2009–15); 60495 (August 13, 2009), 74 FR 41957 (August 19, 2009) (SR–NYSEArca–2009–72); and 66379 (February 10, 2012), 77 FR 9277 (February 16, 2012) (SR–NYSEArca–2012–11).

[12] With respect to equities traded on the Exchange, the term Market Maker refers to an ETP Holder that acts as a Market Maker pursuant to NYSE Arca Rule 7–E. *See* NYSE Arca Rule 1.1(z). An ETP Holder is a sole proprietorship, partnership, corporation, limited liability company, or other organization in good standing that has been issued an ETP. *See* NYSE Arca Rule 1.1(o).

[13] With respect to equities traded on the Exchange, the term Lead Market Maker refers to registered Market Maker that is the exclusive Designated Market Maker in listings for which the Exchange is the primary listing market. *See* NYSE Arca Rule 1.1(w).

[14] The LMM program was designed to incentivize firms to take on the LMM designation and foster liquidity provision and stability in the market. In order to accomplish this, the Exchange provided LMMs with an opportunity to receive incrementally higher transaction credits and incur incrementally lower transaction fees compared to standard liquidity maker-taker rates.

[15] *See* Securities Exchange Act Release No. 69706 (June 6, 2013), 78 FR 35340 (June 12, 2013) (SR–NYSEArca–2013–34) (''ETP Incentive Program Approval'').

[16] *See* Securities Exchange Act Release No. 72963 (September 3, 2014), 79 FR 53492 (September 9, 2014) (SR–NYSEArca–2014–99).

[17] *See* Securities Exchange Act Release No. 75846 (September 4, 2015), 80 FR 54646 (September 10, 2015) (SR–NYSEArca–2015–78).

[18] *See* Securities Exchange Act Release No. 78497 (August 8, 2016), 81 FR 53524 (August 12, 2016) (SR–NYSEArca–2016–110).

same ETP Holder.[19] In connection with the STP functionality, the Exchange adopted credits and fees for orders returned to an ETP Holder using the STP Modifiers.[20] Currently, ETP Holders entering an incoming order with either the STP Cancel Both (''STPC'') or the STP Decrement and Cancel (''STPD'') Modifier are charged $0.0030 per share for orders returned to the ETP Holder. The ETP Holder's corresponding resting order marked with any of the STP Modifiers that interacts with an incoming STPC or STPD Modifier is credited $0.0029 per share for orders returned to the ETP Holder. The Exchange proposes to modify the credit from $0.0029 per share to $0.0030 per share for an ETP Holder's resting order that is returned to the ETP Holder. The Exchange is not proposing any change to the fees and credits applicable to orders with the STP Cancel Newest and the STP Cancel Oldest Modifiers.

On incoming orders marked with the STPD Modifier, both orders are cancelled back to the ETP Holder if the orders are equivalent in size. If the orders are not equivalent in size, the equivalent size is cancelled back to the ETP Holder and the larger order is decremented by the size of the smaller order with the balance remaining on the NYSE Arca Book. For billing purposes, only the size of the portion of the orders cancelled back to the ETP Holder is charged or credited. On incoming orders marked with the STPC Modifier, the entire size of both orders is cancelled back to ETP Holder. However, for billing purposes, incoming orders marked with the STPC Modifier are only charged or credited up to the equivalent size of both orders.[21]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[23] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed revised Step-Up Tier is equitable because it is open to all ETP Holders and Market Makers on an equal basis and provides credits that are reasonably related to the value to an exchange's market quality associated with higher volumes. As stated above, the Exchange believes that the Step-Up Tier is intended to incentivize market participants to increase the orders sent directly to NYSE Arca and therefore provide liquidity that supports the quality of price discovery and promotes market transparency. Moreover, the addition of the Step-Up Tier would benefit market participants whose increased order flow provides meaningful added levels of liquidity thereby contributing to the depth and market quality on the Exchange. The Exchange believes that the proposed change is equitable and not unfairly discriminatory because providing incentives for orders that are executed on a registered national securities exchange would contribute to investors' confidence in the fairness of their transactions and would benefit all investors by deepening the Exchange's liquidity pool, supporting the quality of price discovery, promoting market transparency and improving investor protection.

The Exchange believes that the proposed NBBO Setter Tier is reasonable because it provides an opportunity for ETP Holders and Market Makers that qualify to receive an incremental per share credit if the ETP ID associated with an ETP Holder or Market Maker meets certain trading qualifications and establishes the BBO on the Exchange.[24] Thus the credit provides incentive to members to provide aggressively priced orders that improve the market by setting the BBO on the Exchange. The Exchange believes that it is reasonable to adopt higher credit to Tape A and Tape C securities because it desires to improve the market on the Exchange in those securities in terms of setting the BBO, which is currently not as robust as price setting in Tape B securities. The Exchange further believes that providing a credit for qualifying orders in Tape C securities beyond the Tape C Tier 2 cap is reasonable as it would create an additional incentive for participants to quote aggressively on the Exchange, which would benefit all investors by deepening the Exchange's liquidity pool, improving displayed prices and promoting market transparency. The Exchange believes the proposed pricing tier is equitable and not unfairly discriminatory because the per share credit(s) under the BBO Setter Tier would be available to all ETP Holders' and Market Makers' ETP IDs on an equal basis and provides an incremental credit for activity that improves the Exchange's market quality through increased activity and by encouraging the setting of the BBO. In this regard, the BBO Setter Tier is intended to encourage higher levels of liquidity provision into the price discovery process and is consistent with the overall goals of enhancing market quality.

The Exchange believes that it is reasonable to delete obsolete pricing tiers from the Fee Schedule because ETP Holders and Market Makers have not increased their activity to qualify for the Tape A and Tape C Tier as significantly as the Exchange anticipated they would. The Exchange believes that it is equitable and not unfairly discriminatory to eliminate the Tape A and Tape C Tier because, as proposed, such pricing tier would be eliminated entirely—ETP Holders and Market Makers would no longer be able to qualify for this pricing tier. This aspect of the proposed rule change would result in the removal of obsolete text from the Fee Schedule and therefore add greater clarity to the Fee Schedule.

The Exchange believes that it is reasonable to eliminate the credits that apply to IOIs submitted by ETP Holders that result in routed and executed orders because the IOI Credits have not incentivized ETP Holders to participate in the IOI program as anticipated by the Exchange. The Exchange believes that it is equitable and not unfairly discriminatory to eliminate the IOI Credits because, as proposed, such credits would be eliminated entirely—ETP Holders would no longer be able to qualify for such credits.

The Exchange believes it is equitable, reasonable and not unfairly discriminatory to remove reference to the ETP Pilot from the Fee Schedule because the ETP Pilot expired in July 2017 and deleting rules that no longer apply will bring clarity to the Fee Schedule. The Exchange believes the proposed rule change will make the Fee Schedule clearer and eliminate potential investor confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and in

[19] *See* Securities Exchange Act Release No. 60191 (June 30, 2009), 74 FR 32660 (July 8, 2009) (SR–NYSEArca–2009–58).

[20] *See* Securities Exchange Act Release No. 60322 (July 16, 2009), 74 FR 36794 (July 24, 2009) (SR–NYSEArca–2009–68). The incoming order (last received order) marked with one of the STP Modifiers controls the billing treatment of both interacting orders marked with STP Modifiers. *See* Schedule of Fees, Self Trade Prevention Modifiers, footnote 6.

[21] *See supra,* note 19.

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(4) and (5).

[24] This is similar to programs currently in place on other exchanges. *See* NBBO Program, Nasdaq Stock Market, at *https://www.nasdaqtrader.com/Trader.aspx?id=PriceListTrading2.*

general, protecting investors and the public interest.

The Exchange believes it is reasonable to modify the credit provided to an ETP Holder's resting STP order that is returned to the ETP Holder. The Exchange believes standardizing the fees and credits applicable to orders marked with the STPC and STPD Modifier would encourage ETP Holders to increase their utilization of the STP functionality in order to better manage order flow and prevent undesirable or unexpected executions with themselves. The Exchange further believes the proposed increased credit is equitable and not unfairly discriminatory because it would be available to all similarly situated ETP Holders on an equal basis.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[25] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the Exchange believes that the proposal to add new pricing tiers would encourage the submission of additional liquidity to a public exchange, thereby promoting price discovery and transparency and enhancing order execution opportunities for ETP Holders and Market Makers. In addition, the removal of pricing tiers and fee credits, and deletion of obsolete text from the Fee Schedule would not have any impact on inter- or intra-market competition because the proposed change would result in a streamlined Fee Schedule. Also, the Exchange believes the proposed increased credit for resting STP orders returned to an ETP Holder would encourage ETP Holders to increase their utilization of the STP functionality in order to better manage order flow and prevent undesirable or unexpected executions with themselves and thus would enhance order execution opportunities for ETP Holders. The Exchange believes that this could promote competition between the Exchange and other execution venues, including those that currently offer similar STP functionality and comparable transaction pricing.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and to attract order flow to the Exchange. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As a result of all of these considerations, the Exchange does not believe that the proposed changes will impair the ability of ETP Holders or competing order execution venues to maintain their competitive standing in the financial markets.

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 foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[26] of the Act and subparagraph (f)(2) of Rule 19b–4[27] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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)[28] 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–NYSEArca–2018–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2018–20. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2018–20, and should be submitted on or before May 8, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–07931 Filed 4–16–18; 8:45 am]

BILLING CODE 8011–01–P

[25] 15 U.S.C. 78f(b)(8).

[26] 15 U.S.C. 78s(b)(3)(A).

[27] 17 CFR 240.19b–4(f)(2).

[28] 15 U.S.C. 78s(b)(2)(B).

[29] 17 CFR 200.30–3(a)(12).

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36172]

JP Rail, Inc. d/b/a Southern Railroad Company of New Jersey—Lease and Operation Exemption—Consolidated Rail Corporation

JP Rail, Inc. d/b/a Southern Railroad Company of New Jersey (SRNJ), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease from Consolidated Rail Corporation (Conrail),[1] a Class III railroad, and to operate an approximately 10.86-mile rail line, known as the Salem Running Track and the Swede Industrial Track, which extends from a point 125 feet +/− south of the southern edge of South Barber Avenue in the City of Woodbury, to milepost 10.86, at the southeast corner of Auburn Road in the Borough of Swedesboro, all in Gloucester County, N.J. (the Line). SRNJ states that the Line includes a public delivery track connected to the Salem Running Track near its northern terminus but does not include the Penns Grove Wye.

According to SRNJ, it is entering into a lease agreement and an interchange agreement with Conrail, which would allow SRNJ to operate over the Line and interchange railcars with Conrail at an interchange track located in the City of Woodbury.

SRNJ certifies that its projected revenues will not exceed those that would qualify it as a Class III rail carrier and will not exceed $5 million. SRNJ states that the agreement does not involve a provision or agreement that may limit future interchange with a third party connecting carrier.

The transaction may be consummated on or after May 2, 2018, the effective date of the exemption (30 days after the verified notice was filed).[2]

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than April 24, 2018 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36172, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, a copy must be served on John K. Fiorilla, Capehart & Scatchard, P.A., 8000 Midlantic Drive, Suite 300S, Mount Laurel, NJ 08054.

According to SRNJ, this action is exempt from environmental review under 49 CFR 1105.6(c) and exempt from historic review under 49 CFR 1105.8(b).

Board decisions and notices are available on our website at ''*WWW.STB.GOV*.''

Decided: April 11, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Raina Contee,

Clearance Clerk.

[FR Doc. 2018–08024 Filed 4–16–18; 8:45 am]

BILLING CODE 4915–01–P

[1] SRNJ states that Conrail is indirectly owned by CSX Corporation and Norfolk Southern Corporation.

[2] SRNJ has requested that the effective date of the exemption be advanced to May 1, 2018, so that operations may commence on that date. This request will be addressed in a separate decision.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Eighty Eighth RTCA SC–147 Plenary Session Joint With EUROCAE WG–75

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

ACTION: Eighty Eighth RTCA SC–147 Plenary Session Joint With EUROCAE WG–75.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Eighty Eighth RTCA SC–147 Plenary Session Joint with EUROCAE WG–75.

DATES: The meeting will be held May 18, 2018 9:00 a.m.–3:30 p.m.

ADDRESSES: The meeting will be held at: RTCA Headquarters, 1150 18th Street NW, Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Al Secen at *asecen@rtca.org* or 202–330–0647, or The RTCA Secretariat, 1150 18th Street NW, Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or website at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Eighty Eighth RTCA SC–147 Plenary Session Joint with EUROCAE WG–75. The agenda will include the following:

1. *Thursday, May 17 (and Possibly Friday May 18), 2018*
2. Opening Plenary Session
   - A. Chairmen's Opening Remarks/ Introductions
   - B. DFO Statement and RTCA Policies
   - C. Approval of Minutes from 87th Meeting of SC–147
   - D. Approval of Agenda
   - E. Future Meeting Scheduling
3. Updates on TSO Schedule, CERT Plan and Final Products (30 min/ 945–1015)
4. SC–147 TOR Revisions
   - A. Final MASPS for Interoperability of Collision Avoidance Systems Language
5. ACAS XA/XO MOPS
6. Final Review and Comment/Open Consultation Overview
7. Working Group Comment Resolution Review and Status
8. Open Comments
   - A. Discussion
9. ACAS XA/XO MOPS Approval Consideration
10. Next Steps
    - A. Comment Resolution Implementation Work–Plan
    - B. European Validation Process/ Schedule
11. ACAS XU
    - I. Report from ACAS XU WG
12. Summary and Adjourn
13. *Note: Plenary May Continue to Friday, May 18th Only if All Business is not Concluded on Thursday, May 17th.*

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

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

Michelle Swearingen,

Systems and Equipment Standards Branch, AIR–6B0, Policy and Innovation Division, AIR–600, Federal Aviation Administration.

[FR Doc. 2018–07953 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2018–0026]

Agency Information Collection Activities: Request for Comments for the Renewal of a Previously Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of

1995, this notice announces that FHWA will submit the collection of information described below to the Office of Management and Budget (OMB) for review and comment. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on February 8, 2018. The PRA submission describes the nature of the information collection and its expected cost and burden.

DATES: Please submit comments by May 17, 2018.

ADDRESSES: You may submit comments identified by DOT Docket ID 2018–0026 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.*. Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Steven Jessberger, 202–366–5052, Federal Highway Administration, Department of Transportation, Office of Highway Policy Information, 1200 New Jersey Avenue SE, Washington, DC 20590, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Travel Monitoring Analysis System (TMAS).

OMB Control Number: 2125–0587.

Background: Title 49, United States Code, Section 301, authorizes the DOT to collect statistical information relevant to domestic transportation. The FHWA is continuing to develop the TMAS to house data that will enable analysis of the amount and nature of both vehicular and nonmotorized travel at the national and regional levels. The information will be used by the FHWA and other DOT agencies to evaluate changes in vehicular and nonmotorized travel to assess impacts on highway safety, national travel trend, national travel demand, the role of travel in economic productivity, impacts of changes in truck travel on infrastructure condition, and maintenance of our Nation's mobility while protecting the human and natural environment. The increasing dependence on truck transport requires that data be available to better assess its overall contribution to the Nation's well-being. In conducting the data collection, the FHWA will be requesting that State Departments of Transportations (SDOTs) report traffic volume, vehicle classification, vehicle weight data and nonmotorized data which they collect as part of their existing traffic monitoring programs, including other sources such as local governments and traffic operations. States and local governments collect nonmotorized and motorized traffic volume, vehicle classification data, and vehicle weight data throughout the year using detection devices. The data should be representative of all public roads within State boundaries. The data will allow transportation professionals at the Federal, State, and metropolitan levels to make informed decisions about policies and plans.

Respondents: 52 SDOTs, including the District of Columbia and Puerto Rico.

Frequency: Annually.

Estimated Average Burden per Response: Each of the SDOTs already collect traffic data for various purposes. In accordance with 23 U.S.C. 303, each State has a Traffic Monitoring System in place so the data collection burden relevant for this notice is the additional burden for each State to provide a copy of their traffic data using the record formats specified in the *Traffic Monitoring Guide.* Automation and online tools continue to be developed in support of the TMAS and the capability now exists for online submission and validation of total volume data. The estimated average monthly burden is 2.5 hours for an annual burden of 30 hours.

Estimated Total Annual Burden Hours: Total burden will be 1,560 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection of information is necessary for the U.S. DOT's performance, including whether the information will have practical utility; (2) the accuracy of the U.S. DOT's estimate of the burden of the proposed information collection; (3) ways to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued On: April 11, 2018.

Michael Howell,

Information Collection Officer.

[FR Doc. 2018–07985 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2018–0023]

Agency Information Collection Activities: Request for Comments for the Renewal of a Previously Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that FHWA will submit the collection of information described below to the Office of Management and Budget (OMB) for review and comment. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on February 8, 2018. The PRA submission describes the nature of the information collection and its expected cost and burden.

DATES: Please submit comments by May 17, 2018.

ADDRESSES: You may submit comments identified by DOT Docket ID 2014–0028 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Samantha Lubkin, 202–366–1575, Office of Bridges and Structures, Federal Highway Administration, Department of Transportation, 1200 New Jersey

Avenue SE, Washington, DC 20590, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: National Bridge Inspection Program.

Background: This collection is necessary to meet legislative requirements of Title 23 United States Code section 144, and the Code of Federal Regulations, 23 Highways Part 650, Subpart C—National Bridge Inspection Standards which require States, Federal Agencies, and Tribal Governments to: (1) Perform and report inventory data from routine inspections, fracture critical inspections, and underwater inspections as appropriate for all highway bridges on public roads, and element level inspections for highway bridges on the National Highway System; (2) report costs associated with the replacement of structurally deficient bridges; and (3) follow up on critical findings. The bridge inspection and replacement cost information that is provided to the FHWA is on an annual basis. The critical findings information is periodically provided to the FHWA. The bridge information is used for multiple purposes, including: (1) The determination of the condition of the Nation's bridges which is included in a biennial report to Congress on the Status of the Nation's Bridges; (2) for various additional reports to Congress on Bridge Safety; (3) the data source for executing various sections of the Federal-aid program which involve highway bridges; (4) the data source for assessing the bridge penalty provisions of Title 23 United States Code section 119; (5) the data source for the evaluation of bridge performance measures established in Title 23 United States Code section 150; (6) for conducting oversight of the National Bridge Inspection Program at the State, Federal agency, and Tribal level; and (7) for strategic national defense needs.

Respondents: 52 State highway agencies including the District of Columbia and Puerto Rico, Federal Agencies, and Tribal Governments. The number of inspections per respondent varies in accordance with the National Bridge Inspection Standards.

Estimated Average Burden per Response: The estimated average burden for each bridge inspection is 8 hours. The estimated average burden for each element level inspection is 25 minutes. The estimated average burden for each cost collection report is 90 hours. The estimated average burden for follow up on critical findings is 40 hours.

Estimated Total Annual Burden Hours: The annual burden hours associated with this renewal is 2,496,990 hours. This estimated figure is based on 307,500 annual instances for routine, fracture critical, and underwater inspections multiplied by 8 hours (2,460,000 hours); plus 72,552 annual element inspections multiplied by 25 minutes (30,230 hours); plus 90 hours for each cost report multiplied by 52 reports (4,680 hours); plus 40 hours for follow up on critical findings multiplied by 52 respondents (2,080 hours) for a combined annual burden of 2,496,990 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection of information is necessary for the U.S. DOT's performance, including whether the information will have practical utility; (2) the accuracy of the U.S. DOT's estimate of the burden of the proposed information collection; (3) ways to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued On: April 11, 2018.

Michael Howell,

Information Collection Officer.

[FR Doc. 2018–07989 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2018–0024]

Agency Information Collection Activities: Request for Comments for the Renewal of a Previously Approved Information Collection.

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that FHWA will submit the collection of information described below to the Office of Management and Budget (OMB) for review and comment. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on February 8, 2018. The PRA submission describes the nature of the information collection and its expected cost and burden.

DATES: Please submit comments by May 17, 2018.

ADDRESSES: You may submit comments identified by DOT Docket ID 2014–0027 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Emergency Relief Funding Applications.

OMB Control Number: 2125–0525.

Background: Congress authorized in Title 23, United States Code, Section 125, a special program from the Highway Trust Fund for the repair or reconstruction of Federal-aid highways and roads on Federal lands which have suffered serious damage as a result of natural disasters or catastrophic failures from an external cause. This program, commonly referred to as the Emergency Relief or ER program, supplements the commitment of resources by States, their political subdivisions, or other Federal agencies to help pay for unusually heavy expenses resulting from extraordinary conditions. The applicability of the ER program to a natural disaster is based on the extent and intensity of the disaster. Damage to highways must be severe, occur over a wide area, and result in unusually high expenses to the highway agency. Examples of natural disasters include floods, hurricanes, earthquakes, tornadoes, tidal waves, severe storms, and landslides. Applicability of the ER program to a catastrophic failure due to an external cause is based on the criteria that the failure was not the result of an inherent flaw in the facility but was sudden, caused a disastrous impact on transportation services, and resulted in unusually high expenses to the highway agency. A bridge suddenly collapsing after being struck by a barge is an

example of a catastrophic failure from an external cause. The ER program provides for repair and restoration of highway facilities to pre-disaster conditions. Restoration in kind is therefore the predominate type of repair expected to be accomplished with ER funds. Generally, all elements of the damaged highway within its cross section are eligible for ER funds. Roadway items that are eligible may include: Pavement, shoulders, slopes and embankments, guardrail, signs and traffic control devices, bridges, culverts, bike and pedestrian paths, fencing, and retaining walls. Other eligible items may include: Engineering and right-of-way costs, debris removal, transportation system management strategies, administrative expenses, and equipment rental expenses. This information collection is needed for the FHWA to fulfill its statutory obligations regarding funding determinations for ER eligible damages following a disaster. The regulations covering the FHWA ER program are contained in 23 CFR part 668.

Respondents: 50 State Transportation Departments, the District of Columbia, Puerto Rico, Guam, American Samoa, Northern Mariana Islands, and the Virgin Islands.

Estimated Average Annual Burden: The respondents submit an estimated total of 30 applications each year. Each application requires an estimated average of 250 hours to complete.

Estimated Total Annual Burden Hours: Total estimated average annual burden is 7,500 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection of information is necessary for the U.S. DOT's performance, including whether the information will have practical utility; (2) the accuracy of the U.S. DOT's estimate of the burden of the proposed information collection; (3) ways to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued On: April 11, 2018.

Michael Howell,

Information Collection Officer.

[FR Doc. 2018–07986 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highways in Colorado

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

ACTION: Notice of limitation on claims for judicial review of actions by FHWA and other Federal agencies.

SUMMARY: This notice announces actions taken by the FHWA and other Federal agencies that are final. The actions relate to various proposed highway projects in the State of Colorado. Those actions grant licenses, permits, and approvals for the projects.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on any of the listed highway projects will be barred unless the claim is filed on or before September 14, 2018. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Stephanie Gibson, Environmental Program Manager, Federal Highway Administration Colorado Division, 12300 W Dakota Avenue, Suite 180, Lakewood, Colorado 80228, telephone: 720–963–3013, email: *Stephanie.Gibson@dot.gov.* Normal business hours are 8:30 a.m. to 5:00 p.m. (Mountain time), Monday through Friday, except Federal Holidays. You may also contact David Singer, NEPA Program Manager, Colorado Department of Transportation, 4201 E. Arkansas Avenue, Shumate Building, Denver, Colorado 80222, 303–757–9878, *David.Singer@state.co.us,* normal business hours are 8:00 a.m. to 4:30 p.m. (Mountain time), Monday through Friday, except Federal Holidays.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA and other Federal agencies have taken final agency actions 23 U.S.C. 139(l)(1) by issuing licenses, permits, and approvals for the highway projects in the State of Colorado that are listed below. The actions by the Federal agencies on a project, and the laws under which such actions were taken, are described in the environmental assessment (EA) or environmental impact statement (EIS) issued in connection with the project and in other key project documents. The EA or EIS, and other key documents for the listed projects are available by contacting the FHWA or the Colorado Department of Transportation at the addresses provided above. The EA, Finding of No Significant Impact (FONSI), Final EIS, and Record of Decision (ROD) documents can be viewed and downloaded from the websites listed below.

This notice applies to all Federal agency decisions on each project as of the issuance date of this notice and all laws under which such actions were taken. This notice does not, however, alter or extend the limitation period of 150 days for challenges to final agency actions subject to previous notices published in the **Federal Register**.

This notice applies to all Federal agency decisions, actions, approvals, licenses and permits on the project as of the issuance date of this notice, including but not limited to those arising under the following laws, as amended:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4370h]; Federal-Aid Highway Act [Title 23] and associated regulations [CFR part 23].

2. *Air:* Clean Air Act, [42 U.S.C. 7401–7671(q)] (transportation conformity); Intermodal Surface Transportation Efficiency Act of 1991, Congestion Mitigation and Air Quality Improvement Program (Sec. 1008 U.S.C. 149).

3. *Land:* Section 4(f) of The Department of Transportation Act: [49 U.S.C. 303] Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209]. Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6901, *et seq.*); Landscaping and Scenic Enhancement (Wildflowers) [23 U.S.C. 319].

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(e)]; Migratory Bird Treaty Act [16 U.S.C. 703–712]. Plant Protection Act [7 U.S.C. 7701 *et seq.*].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, [54 U.S.C. 306108]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–470(mm)]; Archeological and Historic Preservation Act [16 U.S.C. 469–469c–2]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Native American Grave Protection and Repatriation Act [25 U.S.C. 3001–3013].

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; Uniform Relocation Assistance and Real Property Acquisition Act [42 U.S.C. 61].

7. *Wetlands and Water Resources:* Clean Water Act [33 U.S.C. 1251–1387 (Sections 319, 401, 404, and 408)]; Land and Water Conservation Fund Act [16 U.S.C. 460l–4–460l–11]; Safe Drinking Water Act [42 U.S.C. 300f—300j–9.]; Flood Disaster Protection Act [42 U.S.C. 4001–4129].

8. *Hazardous Materials:* Comprehensive Environmental Response, Compensation, and Liability Act [42 U.S.C. 9601–9675]; Superfund Amendments and Reauthorization Act of 1986 [Pub. L. 99–499]; Resource Conservation and Recovery Act [42 U.S.C. 6901–6992(k)].

9. *Executive Orders:* E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 11988 Floodplain Management; E.O. 11990 Protection of Wetlands; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 13007 Indian Sacred Sites; E.O. 13112 Invasive Species; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 13287 Preserve America.

The projects subject to this notice are:

1. I–76 and Bridge Street Interchange EA and FONSI. Project Location: I–76 and Bridge Street, Brighton, Colorado. Project reference number: 0761–202. Project overview: The project would construct a new interchange at I–76 and Bridge Street (SH 7). Project Purpose: The purpose of the project is to increase local and regional east-west connectivity, reduce the amount of travel delay through the planning horizon year of 2035, and improve traffic flow in the project area. Signed NEPA documents and permits: EA was signed January 23, 2015 and FONSI was signed July 8, 2015. *https://www.brightonco.gov/605/I-76-and-Bridge-Street-Interchange-Proje* and *https://www.codot.gov/library/studies/i76bridgestreetea.*

2. 6th Avenue Parkway Extension EA and FONSI. Project Location: 6th Avenue from SH 30 to E–470, Aurora, Colorado. Project overview: This project would construct the 6th Avenue Parkway extension along a new roadway alignment between State Highway (SH 30) and the 6th Avenue Parkway/E–470 Tollway (E–470) interchange Project Purpose: The purpose of this project is to enhance east-west mobility by implementing a transportation solution that will close a critical gap between SH 30 and E–470 in the regional transportation network of northeastern Aurora. Signed NEPA documents and permits: EA signed June 23, 2016 and FONSI signed December 8, 2016. *https://www.auroragov.org/business_services/planning/plans_and_studies/transportation_planning/6th_avenue_parkway_extension/* and *https://www.codot.gov/projects/sixth-avenue-parkway-extension-to-e-470.*

3. Martin Luther King, Jr. Boulevard Extension EA and FONSI. Project Location: Near Havana Way, between Havana Street and Peoria Street, Denver, Colorado. Project reference number: STU M320–099. Project overview: The existing Havana Way would be renamed MLK Blvd., widened to a four-lane arterial, and extended east to the Peoria Street and Fitzsimons Parkway intersection. Project Purpose: The purpose of the project is to improve an east-west arterial connection between Havana Street and Peoria Street, a distance of 1.1 miles, improving traffic congestion and reducing out-of-direction travel. Signed NEPA documents and permits: EA signed July 25, 2011 and FONSI signed October 19, 2017. *https://www.denvergov.org/content/denvergov/en/denver-department-of-public-works/projects/current/mlk-boulevard-extension.html.*

4. US 50 West, Wills Blvd. to McCulloch Blvd. (Milepost 313 to Milepost 307) EA and FONSI. Project Location: US 50 in the western part of Pueblo, Colorado. Project reference number: STA 0503–088. Project overview: The project would widen US 50 from four to six lanes, and change intersections to interchanges at US 50 at Purcell Blvd. and Pueblo Blvd. Project Purpose: The purpose of the project is to improve safety; increase mobility, such as reducing travel time, relieving traffic congestion; and improve level of service to the connecting road network. Signed NEPA documents and permits: EA signed April 21, 2016 and FONSI signed August 17, 2016. *https://www.codot.gov/library/studies/us50ea.*

5. North I–25 EIS and RODs. Project Location: I–25 corridor from Denver to Wellington in northern Colorado. Project reference number: IM 0253(179). Project overview: The I–25 North project is an improvements project that includes; general purpose lanes, tolled express lanes, interchange reconstruction, and multi-modal services such as: I–25 express bus, US 85 commuter bus, and commuter rail service. Project purpose: The purpose of the I–25 North project is to make improvements to provide modal alternatives, correct geometric deficiencies, improve safety, mobility and accessibility, and replace aging and obsolete infrastructure. Signed NEPA documents and permits: FEIS was signed August 19, 2011. Revised ROD1 (SH 392 to SH 14) was signed August 16, 2017. Revised ROD1 (I–25/SH 7 Interchange) was signed October 20, 2017. ROD2 (120th Avenue to SH 7) was signed September 28, 2015. ROD3 (Crossroads Boulevard) was signed June 8, 2016. ROD4 (SH 56 to SH 392) was signed April 27, 2017. ROD5 (Vine Drive/County Road 48 Bridge Replacement) was signed December 1, 2017. *https://www.codot.gov/projects/north-i-25-eis/Northi25rod.*

6. US 50 Tier 1 Combined Final EIS and ROD. Project Location: A 150-mile-long portion of US 50 between Pueblo and the vicinity of the Colorado-Kansas state line, going through Pueblo, Otero, Bent, and Prowers Counties. Project reference number: NH 0504–037. Project overview: The Build Alternative consists of constructing a four-lane expressway on or near the existing US 50 alignment, including new alignments around ten towns to preserve their business districts and historic downtown areas. Project Purpose: The purpose of the project is to improve safety and mobility for local, regional, and long-distance users of US 50 for present and future travel demand. This will be accomplished by balancing the mobility and access needs of these users and also providing the flexibility to meet future travel demands. Signed NEPA documents and permits: The Combined Final EIS/ROD was signed on December 11, 2017. *https://www.codot.gov/projects/us50e.*

7. Colorado State Highway 470 (C–470) Corridor, Kipling Parkway to I–25 EA and FONSI. Project Location: A 13.75-mile portion of C–470 in the southern portion of the Denver metropolitan area. Project reference number: NH 4701–103. Project overview: The project involves adding one managed, tolled express lane in each direction between I–25 and Kipling Parkway, and a second managed lane as follows: Westbound, I–25 to Lucent Boulevard, and eastbound, Broadway to I–25. The purpose of the project is to provide congestion relief, decrease travel delay, and improve corridor reliability between Kipling Parkway and I–25 on the C–470 corridor. Project Purpose: The purpose of the project is to address existing and future C–470 congestion between Kipling Parkway and I–25, reduce traveler delay, and improve travel time reliability for corridor users through the year 2035. Signed NEPA documents and permits: This statute of limitations notice applies

to the Reevaluation signed on March 28, 2018 that provided additional detail to the noise analysis that was contained in the Revised Environmental Assessment (EA) (signed on July 24, 2015) and the Finding of No Significant Impact (FONSI) (signed on November 20, 2015). The statute of limitations notice for the FONSI expired on May 16, 2016.

Authority: 23 U.S.C. 139(l)(1).

Issued on: April 2, 2018.

John M. Cater,

Division Administrator, Lakewood, Colorado.

[FR Doc. 2018–07877 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2011–0382; FMCSA–2011–0383; FMCSA–2013–0194; FMCSA–2014–0012; FMCSA–2014–0013; FMCSA–2015–0342; FMCSA–2015–0343; FMCSA–2016–0034]

Qualification of Drivers; Exemption Applications; Diabetes

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 191 individuals from its prohibition in the Federal Motor Carrier Safety Regulations (FMCSRs) against persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. The exemptions enable these individuals with ITDM to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below. Comments must be received on or before May 17, 2018.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2011–0382; FMCSA–2011–0383; FMCSA–2013–0194; FMCSA–2014–0012; FMCSA–2014–0013; FMCSA–2015–0342; FMCSA–2015–0343; FMCSA–2016–0034 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number(s) for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day e.t., 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments online.

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

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5:30 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for five years if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding diabetes found in 49 CFR 391.41(b)(3) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control.

The 191 individuals listed in this notice have requested renewal of their exemptions from the diabetes standard in 49 CFR 391.41(b)(3), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable two-year period.

II. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

III. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 191 applicants has satisfied the renewal conditions for obtaining an exemption from the diabetes requirement (77 FR 10612; 77 FR 13686; 77 FR 20874; 77 FR 25227; 79 FR 6987; 79 FR 10612; 79 FR 14579; 79 FR 18388; 79 FR 27685; 79 FR 28590; 81 FR 10703; 81 FR 14179; 81 FR 14197; 81 FR 39318; 81 FR 40743; 81 FR 42043; 81 FR 85317). They have maintained their required medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous two-year exemption period. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each of these drivers for a period of two years is likely to achieve a level of

safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315, the following groups of drivers received renewed exemptions in the month of April and are discussed below:

As of April 1, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 84 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (79 FR 6987; 79 FR 18388; 81 FR 10703; 81 FR 40743; 81 FR 85317):

Dennis D. Basmajian (PA)
Glen A. Bayne (ND)
John R. Benshoff (OH)
Harry Berrios (MA)
Terry D. Bettcher (NE)
Jeremy S. Beyerl (PA)
Robert P. Blum (IA)
Mario Boccio (FL)
Christopher J. Branham (SC)
Willard A. Brown (VA)
Terrence K. Cannon (IL)
Candace L. Coccimiglio (PA)
Matthew C. Costa (MA)
Joseph F. Coyle (KY)
Robert P. Crisp (SD)
Philip W. Cumbie (AL)
John H. Cuppett (GA)
Quentin W.S. Dasilva (PA)
Trisha J. Davis (ME)
Eudes N. De Leon (PA)
Randal L. DeBord (TN)
Aleksandr Faynkikh (NY)
Paul D. Ferris (NY)
Berry C. Feuerbacher (AR)
Isaac W. Fitzgerald (UT)
Alex C. Ford (IL)
Robert C. Freeman (VA)
Timothy D. Frye (MA)
Larry Gaskill (RI)
Thomas H. Gaskins (NC)
Samuel J. Gonzales (NM)
Gary A. Grant (WA)
Brian C. Halcomb (IL)
Steven R. Hatch (MI)
William D. Herman (MN)
Floyd E. Holt (VA)
Randall L. Jastram (SD)
Thomas M. Johnson (NM)
Steven R. Jordan (NC)
Kevin A. Kane (NY)
Ryan B. Kincade (CA)
William M. LaPrade (VA)
Gerald Lee (CA)
Timothy R. Lewis (OR)
Gregory J. Littlefield (MN)
John Malloy (PA)
James W. McMenamin (PA)
Glen H. Miller (MI)
Daniel J. Milles, Jr. (FL)
Miguel A. Molina (CO)
Douglas B. Murrell (IN)
Joshua A. Myers (OH)
William C. Nelson (IA)
Howard L. Nelson (IA)
Chris R. Niles (WA)
Keith E. Osterbaan (MI)
Ryan M. Ottis (ND)
Bolaji B. Oyegbola (DC)
Steven M. Parsons (WV)
Teddy D. Peller (AL)
Jeffrey P. Peloquin (NC)
Scott A. Pietruszynksi (IL)
William L. Reece (ND)
John P. Reed, III (DE)
Randy D. Rinnels (IA)
Denise D. Ruffin (MS)
Thomas W. Scott, Jr. (PA)
Charles L. Spencer (NY)
Ryan E. Stretch (MO)
William F. Sullivan, IV (NY)
Robert B. Thomas (PA)
John R. Thompson (WI)
Raymond L. Torrez (MI)
Bore Trivuncic (FL)
William M. Turner (NJ)
Everette L. Twyman (MO)
James H. Vogt (IL)
Ronald L. Voigt (MN)
Michael P. Volpe (MA)
John F. Whitesides (NC)
Michael C.J Wilcox (NY)
Donald L. Winslow (ME)
James J. Wolf, Jr. (PA)
Kevin J. Yates (IL)

The drivers were included in docket numbers FMCSA–2013–0194; FMCSA–2015–0342. Their exemptions are applicable as of April 1, 2018, and will expire on April 1, 2020.

As of April 6, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following eight individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (77 FR 10612; 77 FR 20874; 81 FR 85317):

Rick J. Birdsall (NE)
Steven L. Drake (CA)
Benjamin J. Duea (MN)
Jonathan E. Hunsaker (OR)
William D. Larsen (SD)
William W. Simmons (FL)
Ronald O. Snyder (OH)
Douglas J. Wood (NY)

The drivers were included in docket number FMCSA–2011–0382. Their exemptions are applicable as of April 6, 2018, and will expire on April 6, 2020.

As of April 16, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 89 individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (81 FR 14179; 81 FR 14197; 81 FR 39318; 81 FR 42043):

Korey D. Adams (MO)
Harold E. Adams, Sr. (IL)
Jerry J. Altenburg (WI)
Juanita K. Anderson (MN)
Chris L. Austin (AL)
Cory M. Bessette (NY)
Daryl K. Birr (WI)
Samuel E. Bostic (WV)
James R. Burch, II (NC)
Walter L. Butcher, IV (PA)
Russell W. Cadman (CO)
Michael J. Chevalier, Jr. (NJ)
James R. Cockerham (IN)
Alexander W. Coleman (WA)
Earl J. Collier, Jr. (MA)
Michael R. Conley (WI)
Carolyn J. Conover (TN)
Gary R. Craig (PA)
Sebastian Dacruz, Jr. (NJ)
Scott D. Davis (KS)
James D. Deardoff (WA)
Joel R. Farmer (ID)
Samuel M. Feaganes, Jr. (VA)
Ronald Floyd (NY)
Donald W. Fowler, Jr. (NY)
William A. Garrett (GA)
William J. Garrett (SD)
Tyrone B. Gary, Sr. (PA)
Hardy D. Glanzer (ND)
Kevin E. Griebel (SD)
Martin R. Hair (CT)
Bruce T. Hanson (MN)
Darrell E. Holtsoi (NM)
Roger J. Huffsmith (WA)
Arrington Hughes (DC)
Joseph P. Hurston (MA)
Brian K. Hyler (WI)
James A. Iozia (NJ)
Joshua D. Jaramillo (WA)
Keven E. Johnson (TX)
Calvin E. Jones, Jr. (VA)
Jerry M. Kilpatrick (AL)
Rex O. King (IA)
Russell D. Koehler (WI)
Edward D. Krager (PA)
Richard A. Lange (IL)
Michael P. Leggett (WV)
John K. Long (MA)
George S. Luce, Jr. (OH)
Russell J. Luedecker (NJ)
Renee N. Lycksell (WA)
Eugene D. Maessner (ND)
Daniel J. Mandell (NC)
Brady T. Mart (IA)
Jack L. McClintock (PA)
John D. McGinley, Jr. (CA)
Jimmie L. Melton (FL)
Gareth L. Miller (OH)
Jimmy C. Morcom (MI)
Kirk A. Mosier (IA)
Daniel A. Neuens (WI)
Peter J. Niedzwiecki (PA)
Kevin R. OToole (WI)
Mark C. Overbaugh (NY)
Mario A. Papa (RI)
Joseph R. Puliafico (NY)
Neal M. Quinton, Jr. (MA)
Howard G. Rau (MD)
Andrew W. Reid (IN)
Brett M. Rice (PA)

Jacob C. Rojan (IN)
Sholom Rub (NY)
David J. Scimecca (NY)
Ronald D. Smith (IN)
Kenneth W. Swisher (IL)
Melissa Tell (NY)
Jeremy N. Thompson (NY)
Charles R. Thompson, Jr. (KY)
Blane Tor (NJ)
Samuel C. Tracy (WA)
Terry L. Underwood, Jr. (VA)
Aaron M. Vanlanduit (MO)
William O. Wallen (IL)
Steven G. Wehrle (MO)
James H. Wilkey (ID)
Joseph M. Wilson, II (WA)
Joseph A. Wilson, Sr. (MA)
Jefferson Yazzie (NM)
Michael A. Zuke, Sr. (NY)

The drivers were included in docket numbers FMCSA–2015–0343; FMCSA–2016–0034. Their exemptions are applicable as of April 16, 2018, and will expire on April 16, 2020.

As of April 27, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following eight individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (77 FR 13686; 77 FR 25227; 81 FR 85317):

Bobby D. Bennett (GA)
Mark S. Clemence (KS)
Mike W. Holland (IL)
Dan M. McAllister (WI)
Paul F. Rivers (MN)
Marcus V. Romo (ID)
Wayne L. Snyder (OH)
Justin K. Zimmerschied (KS)

The drivers were included in docket number FMCSA–2011–0383. Their exemptions are applicable as of April 27, 2018, and will expire on April 27, 2020.

As of April 30, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following two individuals have satisfied the renewal conditions for obtaining an exemption from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce (79 FR 10612; 79 FR 14579; 79 FR 27685; 79 FR 28590; 81 FR 85317): Charles L. Bryant, (PA); Christopher P. Martin, (NH).

The drivers were included in docket numbers FMCSA–2014–0012; FMCSA–2014–0013. Their exemptions are applicable as of April 30, 2018, and will expire on April 30, 2020.

IV. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must submit a quarterly monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) each driver must report within two business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) each driver must submit an annual ophthalmologist's or optometrist's report; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

V. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VI. Conclusion

Based upon its evaluation of the 191 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the rule prohibiting drivers with ITDM from driving CMVs in interstate commerce. In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years unless revoked earlier by FMCSA.

Issued on: April 2, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018–07988 Filed 4–16–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Information Collection; Comment Request

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments should be received on or before June 18, 2018 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: To obtain additional information, or copies of the information collection and instructions, or copies of any comments received, contact LaNita Van Dyke, at (202) 317–6009, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Request for Comments

The Internal Revenue Service, as part of their continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to take this opportunity to comment on the proposed or continuing information collections listed below in this notice, as required by the Paperwork Reduction Act of 1995, (44 U.S.C. 3501 *et seq.*).

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments will become a matter of public record. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether the collection of information is necessary for the proper performance of the agency's functions, including whether the information has 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 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 the requested information.

The IRS is seeking comments concerning the following form, and reporting and record-keeping requirements:

Title: Distributions From an HSA, Archer MSA or Medical Advantage MSA.

OMB Number: 1545–1517.

Form Number: 1099–SA.

Abstract: This form is used to report distributions from a medical savings account as required by Internal Revenue Code section 220(h).

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 25,839.

Estimated Time per Response: 8 min.

Estimated Total Annual Burden Hours: 3,618.

The following paragraph applies to the collection 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.

Approved: April 10, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–07967 Filed 4–16–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900—NEW]

Agency Information Collection Activity: Pulmonary Health and Deployment to Southwest Asia and Afghanistan

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Health Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before May 17, 2018.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–NEW'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia D. Harvey-Pryor, Office of Quality, Privacy and Risk (OQPR), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–NEW'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 CFR part 16.

Title: Pulmonary Health and Deployment to Southwest Asia and Afghanistan.

OMB Control Number: 2900–NEW.

Type of Review: New collection.

Abstract: The Department of Veterans Affairs Cooperative Studies Program (CSP) is conducting a human subjects research study to understand the association between military deployment to Afghanistan, Iraq, and 5 other countries and current pulmonary function. Data on deployment locations, exposures while deployed, current pulmonary function and several important covariates are not available and will need to be collected from participants. This research study will generate data which will be used to assist VA in obtaining information that can be used to improve health care for Veterans.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 83 FR 2876 on January 19, 2018, pages 2876–2877.

Affected Public: Individuals and households.

Estimated Annual Burden:

Recruitment Screening Module—517 hours.

Spirometry Screening Module—1,033 hours.

Military Overview Module—517 hours.

OEF/OIF/OND Location Module—1,550 hours.

Non-OEF/OIF/OND Location Module—1,550 hours.

OEF/OIF/OND Exposure Module—1,033 hours.

Non-OEF/OIF/OND Exposure Module—1,033 hours.

Civilian Occupation and Hobby Exposure Module—517 hours.

Health, Smoking, and Demographics Module—1,550 hours.

Medication and Dietary Supplement Module—1,033 hours.

Participant Status Check-In Module—517 hours.

Spirometry—3,617 hours.

Medical History Module—517 hours.

Functional Health Module—413 hours.

Health Symptoms Module—310 hours.

Current Mood Module—517 hours.

Participant Feedback Module—310 hours.

Post-Visit Feedback Module—52 hours.

Estimated Average Burden per Respondent:

Recruitment Screening Module—5 minutes.

Spirometry Screening Module—10 minutes.

Military Overview Module—5 minutes.

OEF/OIF/OND Location Module—15 minutes.

Non-OEF/OIF/OND Location Module—15 minutes.

OEF/OIF/OND Exposure Module—10 minutes.

Non-OEF/OIF/OND Exposure Module—10 minutes.

Civilian Occupation and Hobby Exposure Module—5 minutes.

Health, Smoking, and Demographics Module—15 minutes.

Medication and Dietary Supplement Module—10 minutes.

Participant Status Check-In Module—5 minutes.

Spirometry—35 minutes.

Medical History Module—5 minutes.

Functional Health Module—4 minutes.

Health Symptoms Module—3 minutes.

Current Mood Module—5 minutes.

Participant Feedback Module—3 minutes.

Post-Visit Feedback Module—10 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents:

Recruitment Screening Module—6200.

Spirometry Screening Module—6200.
Military Overview Module—6200.
OEF/OIF/OND Location Module—6200.
Non-OEF/OIF/OND Location Module—6200.
OEF/OIF/OND Exposure Module–6200.
Non-OEF/OIF/OND Exposure Module—6200.
Civilian Occupation and Hobby Exposure Module—6200.
Health, Smoking, and Demographics Module—6200.
Medication and Dietary Supplement Module—6200.
Participant Status Check-In Module–6200.
Spirometry—6200.
Medical History Module—6200.
Functional Health Module—6200.
Health Symptoms Module—6200.
Current Mood Module—6200.
Participant Feedback Module—6200.
Post-Visit Feedback Module—310.

By direction of the Secretary.

Cynthia D. Harvey-Pryor,

Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2018–07952 Filed 4–16–18; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0744]

Agency Information Collection Activity: VBA Call Center Satisfaction Survey

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 18, 2018.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0744'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Cynthia D. Harvey-Pryor at (202) 461–5870.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA'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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: The Government Performance and Results Act of 1993, Public Law 103–62. August 3, 1993 and Title 38 U.S.C., § 527, Evaluation and Data Collection; 5 CFR 1320: Section 3506(c)(2)(A) of

Title: VBA Call Center Satisfaction Survey.

OMB Control Number: 2900–0744.

Type of Review: Revision of a currently approved collection.

Abstract: VBA maintains a commitment to improve the overall quality of service for Veterans. Feedback from Veterans regarding their recent experience to the VA call centers will provide VBA with three key benefits to: (1) Identify what is most important to Veterans; (2) determine what to do to improve the call center experience; and (3) serve to guide training and/or operational activities aimed at enhancing the quality of service provided to Veterans and active duty personnel.

Affected Public: Individuals or households.

Estimated Annual Burden: 3,600 hours.

Estimated Average Burden per Respondent: 6 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 36,000.

By direction of the Secretary.

Cynthia D. Harvey-Pryor,

Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2018–07949 Filed 4–16–18; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900—NEW]

Agency Information Collection Activity: Federal Medical Care Recovery Act Bill Requests

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Health Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed new collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 18, 2018.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Brian McCarthy, Office of Regulatory and Administrative Affairs (10B4), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Brian.McCarthy4@va.gov.* Please refer to ''OMB Control No. 2900—NEW'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Brian McCarthy at (202) 615–9241.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506 of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA'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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 501, 38 CFR 1.900 *et seq.*; 42 U.S.C. 2651–2653; 38 U.S.C. 1729; 28 CFR 43.2; and E.O. 9397.

Title: Federal Medical Care Recovery Act Bill Requests; Request for VA Billing, CHAMPVA Request for Billing.

OMB Control Number: 2900—NEW.

Type of Review: New collection.

Abstract: The purpose of collecting this information is to provide basic information from which potential liability can be assessed for VA to recover the cost of care from the liable party instead of the American taxpayer and Veteran paying for the care. Failure to provide any or all of the requested information may delay or result in VA's inability to create accident-related billing, assert a claim for reimbursement, and assist the Veteran in their personal injury or workers compensation claim. Without a third party paying for the care, the Veteran may owe VA copayments. With regards to the CHAMPVA form alone: Failure to provide any or all of the requested information may delay or result in VA's inability to provide CHAMPVA benefits.

Affected Public: Individuals and households.

Estimated Annual Burden:

Request for VA Billing—385 hours.

CHAMPVA Request for Billing—303 hours.

Estimated Average Burden per Respondent:

Request for VA Billing—7 minutes.

CHAMPVA Request for Billing—7 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents:

Request for VA Billing—3,300.

CHAMPVA Request for Billing—2,600.

By direction of the Secretary.

Cynthia D. Harvey-Pryor,

Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2018–07947 Filed 4–16–18; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Programmatic Consideration of Historic Properties in Transfer of Property Rights of Vacant and Underutilized Buildings, Structures and Land

AGENCY: Department of Veterans Affairs.

ACTION: Notice of availability and request for comment.

SUMMARY: The Department of Veterans Affairs (VA) is reviewing its capital asset inventory and identifying vacant and underutilized buildings, structures and land. VA may consider sales, public benefit conveyances, demolition and deconstruction to reduce its unneeded real property. Additionally, VA may consider leases and exchanges to non-Federal entities for potential reuse of vacant and underutilized buildings and structures. This announcement pertains to an alternative process VA may utilize to comply with the requirements of the National Historic Preservation Act (NHPA).

The Advisory Council on Historic Preservation (ACHP) is a Federal agency tasked with review of other Federal agencies' compliance with NHPA and the implementing regulations. VA intends to request ACHP to consider a Program Comment for the entire program of reduction of vacant and underutilized properties. ACHP may agree or decline to consider VA's Program Comment request. If ACHP does issue a Program Comment in lieu of case-by-case review, this alternative will conserve VA's time, budget and staff resources. It will enable VA to transfer real property rights of the vacant and underutilized properties more quickly while still giving consideration to historic properties as required by NHPA.

This Notice of Availability announces and invites public involvement in the process of development of the Program Comment for consideration of historic properties that are vacant and underutilized buildings, structures and land that may be historic properties. Historic properties are those listed on the National Register of Historic Places or eligible for such listing.

DATES: Comments should be submitted within 30 days from when this announcement is published in the **Federal Register**.

ADDRESSES: Written comments may be submitted by email through *http://www.regulations.gov.* Comments should indicate that they are submitted in response to ''Notice of availability and request for comments—Programmatic Consideration of Historic Properties in Transfer of Property Rights of Vacant and Underutilized Buildings, Structures and Land.'' During the comment period, comments may be viewed online through the Federal Docket Management System at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Douglas Pulak, Federal Preservation Officer (003C2), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420.

SUPPLEMENTARY INFORMATION: Section 106 of the National Historic Preservation Act (54 U.S.C. 306108) requires Federal agencies to take into account the effects of their undertakings on historic properties and provide ACHP a reasonable opportunity to comment with regard to such undertakings. ACHP regulations, codified at 36 CFR part 800, set forth the process by which Federal agencies comply with NHPA requirements.

Under Section 800.14(e), Federal agencies may request ACHP to provide a Program Comment on a particular program and category of undertakings in lieu of conducting individual reviews of each individual undertaking as set forth in 36 CFR Sections 800.4 through 800.6. A Federal agency can meet its Section 106 responsibilities for a category of undertakings by taking into account ACHP's Program Comment and by following the steps set forth in those comments.

To initiate this process, VA intends to request ACHP to consider a Program Comment for its program to reduce its real property inventory of vacant and underutilized properties at VA Medical Centers and National Cemeteries nationwide. VA intends the program comment to ACHP will encompass a variety of real estate actions such as leases (including both Enhanced-Use Leases under VA's authority at 38 U.S.C. 8161–8169, and NHPA Section 111 leases authorized under 16 U.S.C. 470h–3), exchanges, sales, transfers, deconstruction and demolition of buildings and structures. ACHP will decide whether to issue a Program Comment to VA or decline. If ACHP decides to issue the Program Comment, they will publish a draft in the **Federal Register** for public review and

comment. Following consideration of such comments by ACHP and VA, the final Program Comment will be published in the **Federal Register**.

VA initiated the identification of historic properties in its capital asset inventory several decades ago. VA identified, in consultation with State Historic Preservation Offices, approximately 65 percent of the medical centers as having some buildings and structures, or districts eligible or listed on the National Register of Historic Places. All of the National Veterans Cemeteries are listed on the National Register. The development of VA and its historic role in the care and treatment of veterans over time is significant in the history of the United States.

The analysis of buildings and structures that are no longer needed or cannot be adapted for current use will aid VA in reducing its real property inventory. Many buildings and structures are not useful for VA's mission. In general, they tend to be warehouses, garages, sheds, animal research structures, and other utilitarian buildings. Most of these types of buildings and structures are not eligible or contributing to a historic district. VA intends to propose deconstruction or demolition of these properties without further consideration under the Program Comment.

For buildings, structures and land that may serve other non-Federal entities purpose, VA may be able to out lease them. The leases would contain specific requirements for treatment of the character defining features of the historic property if the lessee is pursuing tax credits for rehabilitation of the historic property. For all other leases of historic properties, the reuse proposal would be evaluated with the lessee for potential retention of any character defining features such as windows, entry spaces, staircases and historic landscaping. If it is not possible to retain significant historic features of a building or structure, they will be documented prior to removal or alteration.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Jacquelyn Hayes-Byrd, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on April 11, 2018, for publication.

Dated: April 11, 2018.

Jeffrey M. Martin,

Impact Analyst, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2018–07958 Filed 4–16–18; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0074]

Agency Information Collection Activity: Request for Change of Program or Place of Training

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

The VA Form 22–1995 is used to determine the applicant's continued eligibility to educational assistance administered by VA after a change in training or the place where training is pursued.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 18, 2018.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0074'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 632–8924 or FAX (202) 632–8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA'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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–21; 5 CFR 1320, Section 3506(c)(2)(A).

Title: Request for Change of Program or Place of Training (VA Form 22–1995).

OMB Control Number: 2900–0074.

Type of Review: Extension of an approved collection.

Abstract: VA Form 22–1995 is used to determine the applicant's continued eligibility to educational assistance administered by VA after a change in training or the place where training is pursued.

Affected Public: Individuals or households.

Estimated Annual Burden: 57,009 hours.

Estimated Average Burden per Respondent: 15 minutes (Electronic) 20 minutes (Paper).

Frequency of Response: One time.

Estimated Number of Respondents: 184,894.

By direction of the Secretary.

Cynthia D. Harvey-Pryor,

Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2018–07948 Filed 4–16–18; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0790]

Agency Information Collection Activity: Application and Reporting Requirements To Receive Grants

AGENCY: Veterans Health Administration, Department of Veterans Affairs

ACTION: Notice.

SUMMARY: Veterans Health Administration, Department of Veterans

Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 18, 2018.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Brian McCarthy, Office of Regulatory and Administrative Affairs (10B4), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Brian.McCarthy4@va.gov.* Please refer to ''OMB Control No. 2900–0790'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Brian McCarthy at (202) 461–6345.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506 of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA'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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 111–163 Section 307.

Title: Application and Reporting Requirements to Receive Grants under 38 CFR 17.703; VA Form 10–10055, VA Form 10–10056.

OMB Control Number: 2900–0790.

Type of Review: New collection.

Abstract: Section 307 of Title III of the Caregivers and Veterans Omnibus Health Services Act of 2010 (section 307) requires VA to establish a program to provide grants to eligible entities to assist veterans in highly rural areas through innovative transportation services to travel to VA medical centers, and to otherwise assist in providing transportation services in connection with the provision of VA medical care to these veterans. Paragraph (a) of section 307 mandates that VA will award grants to eligible entities for these purposes, and paragraph (b) of section 307 mandates that VA will establish procedures for evaluating grant applications. This collection of information is necessary to fulfill VA's obligations under section 307.

Affected Public: Individuals and households.

Estimated Annual Burden: 200 hours.

Estimated Average Burden per Respondent: 111 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents: 100.

By direction of the Secretary.

Cynthia D. Harvey-Pryor,

Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2018–07951 Filed 4–16–18; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0793]

Agency Information Collection Activity: VA Health Professional Scholarship and Visual Impairment and Orientation and Mobility Professional Scholarship Programs

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Health Administration (VHA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to identify areas for improvement in clinical training programs.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 18, 2018.

ADDRESSES: Submit written comments on the collection of information through the Federal Docket Management System (FDMS) at *www.Regulations.gov*; or to Brian McCarthy, Office of Regulatory and Administrative Affairs, Veterans Health Administration (10B4), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email: *Brian.McCarthy4@va.gov.* Please refer to ''OMB Control No. 2900–0793'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Brian McCarthy at (202) 461–6345.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA'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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Titles:

1. Academic Verification, VA Form 10–0491.
2. Addendum to Application, VA Form 10–0491a.
3. Annual VA Employment Deferment Verification, VA Form 10–0491c
4. Education Program Completion Notice Service Obligation Placement, VA Form 10–0491d
5. Evaluation Recommendation Form, VA Form 10–0491e
6. HPSP Agreement, VA Form 10–0491f
7. HPSP/OMPSP Application, VA Form 10–0491g
8. Notice of Approaching Graduation, VA Form 10–0491h
9. Notice of Change and/or Annual Academic Status Report, VA Form 10–0491i
10. Request for Deferment for Advanced Education, VA Form 10–0491j

11. VA Scholarship Offer Response, VA Form 10–0491k
12. VIOMPSP Agreement, VA Form 10–0491l
13. Mobility Agreement, VA Form 10–0491m

OMB Control Number: 2900–0793.

Type of Review: Revision of a currently approved collection.

Abstracts:

The information required determines the eligibility or suitability of an applicant desiring to receive an award under the provisions of 38 U.S.C. 7601 through 7619, and 38 U.S.C. 7501 through 7505. The information is needed to apply for the VA Health Professional Scholarship Program or Visual Impairment and Orientation and Mobility Professional Scholarship Program. The VA Health Professional Scholarship Program awards scholarships to students receiving education or training in a direct or indirect healthcare services discipline to assist in providing an adequate supply of such personnel for VA and for the United States. The Visual Impairment and Orientation and Mobility Professional Scholarship Program awards scholarships to students pursuing a program of study leading to a degree in visual impairment or orientation and mobility in order to increase the supply of qualified blind rehabilitation specialists for VA and the Nation.

Affected Public: Individuals or households.

Estimated Burden:

APPLICANTS

VA Forms	# of respondents	× # of responses	Equals	× # of minutes	Equals (minutes)	÷ by 60 =	Number of hours
10–0491g—Application	1,500	1	1,500	60	90,000	.....	1,500
10–0491—Academic Verification	1,500	1	1,500	60	90,000	.....	1,500
10–0491e—Evaluation & Recommendation ..	1,500	2	3,000	50	150,000	.....	2,500
10–0491a—Addendum to Application	450 (30%)	1	450	10	4,500	.....	75
Total	.....	.....	.....	.....	.....	.....	5,575

APPLICANTS SELECTED TO RECEIVE A SCHOLARSHIP

VA Forms	# of respondents	× # of responses	Equals	× # of minutes	Equals (minutes)	÷ by 60 =	Number of hours
10–0491m—Mobility Agreement	30	1	30	10	300	.....	5
10–0491L—Agreement for the VIOMPSP	30	1	30	15	450	.....	8
10–0491k—VA Scholarship Offer Response	30	1	30	10	300	.....	5
10–0491i—Notice of Change and/or Annual Academic Status Report	30	1	30	20	600	.....	10
10–0491h—Notice of Approaching Graduation	30	1	30	10	300	.....	5
10–0491d—Education Program Completion Notice/Service Obligation Placement	30	1	30	20	600	.....	10
10–0491j—Request for Deferment for Advanced Education	6	1	6	10	60	.....	1
10–0491c—Annual VA Employment/ Deferment Verification	30	1	24	10	240	.....	4
Total	.....	.....	.....	.....	.....	.....	48
Grand Total for VIOMPSP ...	.....	.....	.....	.....	.....	.....	5,623

HEALTH PROFESSIONAL SCHOLARSHIP PROGRAM (HPSP) APPLICANTS

VA Forms	# of respondents	× # of responses	Equals	× # of minutes	Equals (minutes)	÷ by 60 =	Number of hours
10–0491g—Application	5,000	1	5,000	60	300,000	.....	5,000

HEALTH PROFESSIONAL SCHOLARSHIP PROGRAM (HPSP) APPLICANTS—Continued

VA Forms	# of respondents	× # of responses	Equals	× # of minutes	Equals (minutes)	÷ by 60 =	Number of hours
10–0491—Academic Verification	5,000	1	5,000	60	300,000		5,000
10–0491e—Evaluation & Recommendation	5,000	2	10,000	50	500,000		8,333
10–0491a—Addendum to Application	1500 (30%)	1	1500	10	15,000		250
Total							18,583

APPLICANTS SELECTED TO RECEIVE A SCHOLARSHIP

VA Forms	# of respondents	× # of responses	Equals	× # of minutes	Equals (minutes)	÷ by 60 =	Number of hours
10–0491m—Mobility Agreement	100	1	100	10	1,000		17
10–0491f—Agreement for the HPSP	100	1	100	15	1,500		25
10–0491k—VA Scholarship Offer Response	100	1	100	10	1,000		17
10–0491i—Notice of Change and/or Annual Academic Status Report	100	1	100	20	2,000		33
10–0491h—Notice of Approaching Graduation	100	1	100	10	1,000		17
10–0491d—Education Program Completion Notice/Service Obligation Placement	100	1	100	20	2,000		33
10–0491j—Request for Deferment for Advanced Education	20	1	20	10	200		3
10–0491c—Annual VA Employment/ Deferment Verification	80	1	80	10	800		13
Total							158
Grand Total for HPSP							18,741
Grand Total for Both VIOMP-SP and HPSP							24,364

Frequency of Response: Annually.

By direction of the Secretary.

Cynthia D. Harvey-Pryor,

Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2018–07950 Filed 4–16–18; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 83 Tuesday,

No. 74 April 17, 2018

Part II

Department of Health and Human Services

45 CFR Parts 147, 153, 154, et al.

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147, 153, 154, 155, 156, 157, and 158

[CMS–9930–F]

RIN 0938–AT12

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule sets forth payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs; cost-sharing parameters; and user fees for Federally-facilitated Exchanges and State Exchanges on the Federal platform. It finalizes changes that provide additional flexibility to States to apply the definition of essential health benefits (EHB) to their markets, enhance the role of States regarding the certification of qualified health plans (QHPs); and provide States with additional flexibility in the operation and establishment of Exchanges, including the Small Business Health Options Program (SHOP) Exchanges. It includes changes to standards related to Exchanges; the required functions of the SHOPs; actuarial value for stand-alone dental plans; the rate review program; the medical loss ratio program; eligibility and enrollment; exemptions; and other related topics.

DATES: *Effective Date:* These regulations are effective on June 18, 2018.

FOR FURTHER INFORMATION CONTACT:

Lindsey Murtagh, (301) 492–4106, Rachel Arguello, (301) 492–4263, Alper Ozinal, (301) 492–4178, or Abigail Walker, (410) 786–1725, for general information.

Krutika Amin, (301) 492–5153, for matters related to risk adjustment, and user fees for Federally-facilitated Exchanges and State-Exchanges on the Federal platform.

Adrianne Patterson, (410) 786–0686, or Abigail Walker, (410) 786–1725, for matters related to sequestration.

Melissa Jaffe, (301) 492–4129, for matters related to risk adjustment data validation, cost-sharing reductions, and the premium adjustment percentage.

Lisa Cuozzo, (410) 786–1746, for matters related to rate review.

Jenny Chen, (301) 492–5156, for matters related to establishing a State Exchange, and State Exchanges on the Federal platform.

Emily Ames, (301) 492–4246, for matters related to Navigators and non-Navigator assistance personnel.

Elissa Dines, (301) 492–4388, for matters related to employer-sponsored coverage verification.

Kendra May, (301) 492–4477, for matters related to the requirement to file an income tax return and reconcile APTC and terminations.

Carolyn Kraemer, (301) 492–4197, for matters related to special enrollment periods under part 155.

Amanda Brander, (202) 690–7892, for matters related to exemptions from the individual shared responsibility payment.

Terence Kane, (301) 492–4449, for matters related to income inconsistencies.

Jacob Schnur, (410) 786–7703, for matters related to direct enrollment.

Laura Eldon, (301) 492–4372, for matters related to the Federally-facilitated SHOP.

Shilpa Gogna, (301) 492–4257, for matters related to SHOP in State Exchanges.

Leigha Basini, (301) 492–4380, Rebecca Zimmermann, (301) 492–4396, or Allison Yadsko, (410) 786–1740, for matters related to standardized options, essential health benefits, stand-alone dental plans and other standards for QHP issuers.

Cam Moultrie Clemmons, (206) 615–2338, for matters related to minimum essential coverage.

Christina Whitefield, (301) 492–4172, for matters related to the medical loss ratio program.

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I. Executive Summary

American Health Benefit Exchanges, or ''Exchanges'' (also called ''Marketplaces'') are entities established under the Patient Protection and Affordable Care Act (PPACA) through which qualified individuals and qualified employers can purchase health insurance coverage. Many individuals who enroll in qualified health plans (QHPs) through individual market Exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums, and receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services. The PPACA also established the risk adjustment program, which is intended to mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small group markets, both on and off Exchanges.

Over time, issuer exits and increasing insurance premiums have threatened the stability of the individual and small group Exchanges in many geographic areas. In previous rulemaking, we established provisions and parameters to implement many PPACA provisions and programs. In this final rule, we amend these provisions and parameters, with a focus on enhancing the role of States in these programs and providing States with additional flexibilities, reducing unnecessary regulatory burden

on stakeholders, empowering consumers, and improving affordability.

On January 20, 2017, the President issued an Executive Order which stated that, to the maximum extent permitted by law, the Secretary of HHS and heads of all other executive departments and agencies with authorities and responsibilities under the PPACA should exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the PPACA that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, health care providers, health insurers, patients, recipients of health care services, purchasers of health insurance, or makers of medical devices, products, or medications. In this rule, within the limitations of the current statute, we are finalizing policies to reduce fiscal and regulatory burdens across different program areas, and to support innovative health insurance models.

We are finalizing several changes that would significantly expand the role of States in the administration of the PPACA. We received comments on additional ways to support State Exchanges (SBEs) in adopting innovative approaches to operating and sustaining their Exchanges, and to make the State Exchange on the Federal platform (SBE–FP) model a more appealing and viable model for States. We finalize policies under which States assume a larger role in reviewing the QHP certification standards of network adequacy and essential community providers for the Federally-facilitated Exchanges (FFEs). This will confirm States' traditional role in overseeing their health insurance markets, and reduce the issuer burden associated with having to comply with duplicative State and Federal reviews.

This rule also finalizes several policies that will provide States with greater flexibility. For example, this rule provides States with additional flexibility in applying the definition of EHBs to their markets starting with the 2020 plan year. In addition to granting States more flexibility regulating their markets, we believe this change would permit States to modify EHBs to increase affordability of health insurance in the individual and small group markets. This rule also provides States with significantly more flexibility in how they operate a Small Business Health Options Program (SHOP), permitting them to operate these Exchanges more efficiently, and therefore benefitting States, issuers, employers, and employees. These changes would allow for a more efficient SHOP, such that employers and employees could enroll in SHOP coverage by working with a QHP issuer or SHOP-registered agent or broker. Additionally, the finalized policies provide States more flexibility regarding risk adjustment transfers in their markets. We also make it easier for States to apply for and be granted an adjustment to the individual market medical loss ratio (MLR) standard in their State. We believe this change provides States with an additional tool to help stabilize, innovate and provide relief in their individual markets. Additionally, we make other changes to the MLR program to reduce the burden on issuers.

Risk adjustment continues to be a core program for stabilizing the individual and small group markets both on and off Exchanges, and we are finalizing recalibrated parameters for the HHS risk adjustment methodology. We are also finalizing several changes related to the risk adjustment data validation program that are intended to ensure the integrity of the results of risk adjustment, while alleviating issuer burden.

As we do every year in the HHS notice of benefit and payment parameters final rule, we are finalizing updated parameters applicable in the individual and small group markets. We are finalizing the user fee rate for issuers participating on FFEs and SBE–FPs for 2019 to be 3.5 and 3.0 percent of premiums, respectively. We are finalizing the premium adjustment percentage for 2019, which is used to set the rate of increase for several parameters detailed in the PPACA, including the maximum annual limitation on cost sharing for 2019, the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Internal Revenue Code of 1986 (the Code), and the assessable payment amounts under section 4980H(a) and (b) of the Code. We are finalizing updates to the maximum annual limitations on cost sharing for the 2019 benefit year for cost-sharing reductions plan variations.

We are finalizing a number of changes related to rate review that are intended to reduce regulatory burden on States and issuers in regard to the rate filing process. Specifically, we are exempting student health insurance coverage from Federal rate review requirements, beginning with coverage effective on or after July 1, 2018. We are also modifying the 10 percent threshold for reasonableness review to a 15 percent default threshold.

Recognizing that Exchanges, including the FFEs, face resource constraints, we are changing the requirements regarding Navigators, and the requirements regarding non-Navigator assistance personnel subject to § 155.215, to enable Exchanges to more easily operate these programs with limited resources. Similarly, we are allowing an agent, broker or issuer participating in direct enrollment to have its selected third-party entity conduct operational readiness reviews, rather than requiring that those reviews be conducted by entities approved by HHS.

We also finalize relatively minor adjustments to our programs and rules as we do each year in the HHS notice of benefit and payment parameters. We are finalizing a number of incremental amendments to our policies around coverage, eligibility, enrollment, and affordability exemptions.

We continue to be very interested in exploring ways to improve Exchange program integrity. In the proposed rule, we sought comment on a number of program integrity items, including whether we should consider shortening the length of time the Exchanges are authorized to obtain enrollee tax information, as well as ways to prompt more timely consumer reporting of changes in circumstances during the benefit year that may impact an individual's eligibility for coverage and financial assistance. In addition, we requested comment on any additional program integrity improvements that were not outlined in the proposed rule, but could be beneficial in a future rulemaking.

Finally, as noted in the proposed rule, we intend to consider proposals in future rulemaking that would help reduce drug costs and promote drug price transparency. We also intend to provide guidance on other aspects of Exchange eligibility in the near future. In particular, we intend to reconsider the appropriate thresholds for changes in income that will trigger a data matching inconsistency, processes for denying eligibility for advance subsidies for individuals who fail to reconcile advance payments of the premium tax credit (APTC) on their Federal income tax return, processes for matching enrollment data with the Medicare and Medicaid programs in order to help consumers avoid duplicate enrollments, and the appropriate manner of recalculating APTC following a midyear change in eligibility, and sought comments on each of these issues as we prepare rulemaking on these topics.

Instituting strong program safeguards to ensure that only individuals who are eligible are enrolled in Exchange coverage, and that they are only

receiving the amount of financial assistance for which they are eligible, is essential to ensuring that the Exchanges operate as intended, and is also a key priority for the Administration. We have already taken action to strengthen safeguards around Exchange eligibility, most recently through the implementation of pre-enrollment verification for special enrollment periods; however, we continue to be interested in exploring ways to further safeguard Federal tax dollars flowing through Exchanges.

II. Background

A. Legislative and Regulatory Overview

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this final rule, we refer to the two statutes collectively as the ''Patient Protection and Affordable Care Act'' or ''PPACA.''

Subtitles A and C of title I of the PPACA reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

Section 2701 of the PHS Act, as added by the PPACA, restricts the variation in premium rates charged by a health insurance issuer for non-grandfathered health insurance coverage in the individual or small group market to certain specified factors. These factors are family size, rating area, age and tobacco use.

Section 2701 of the PHS Act operates in coordination with section 1312(c) of the PPACA. Section 1312(c) of the PPACA generally requires a health insurance issuer to consider all enrollees in all health plans (except for grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual market and small group market risk pools under section 1312(c)(3) of the PPACA.

Section 2702 of the PHS Act, as added by the PPACA, requires health insurance issuers that offer health insurance coverage in the group or individual market in a State to offer coverage to and accept every employer and individual in the State that applies for such coverage unless an exception applies.[1]

Section 2703 of the PHS Act, as added by the PPACA, and sections 2712 and 2741 of the PHS Act, as added by the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA) prior to the enactment of the PPACA, require health insurance issuers that offer health insurance coverage in the group or individual market to renew or continue in force such coverage at the option of the plan sponsor or individual unless an exception applies.

Section 2718 of the PHS Act, as added by the PPACA, generally requires health insurance issuers to submit an annual MLR report to HHS, and provide rebates to enrollees if the issuers do not achieve specified MLR thresholds.

Section 2794 of the PHS Act, as added by the PPACA, directs the Secretary of HHS (the Secretary), in conjunction with the States, to establish a process for the annual review of ''unreasonable increases in premiums for health insurance coverage.''[2] The law also requires health insurance issuers to submit to the Secretary and the applicable State justifications for unreasonable premium increases prior to the implementation of the increases. Section 2794(b)(2) of the PHS Act further specifies that beginning with plan years starting in 2014, the Secretary, in conjunction with the States, will monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.

Section 1252 of the PPACA provides that any standard or requirement adopted by a State under title I of the PPACA, or any amendment made by title I of the PPACA, is to be applied uniformly to all health plans in each insurance market to which the standard and requirement apply.

Section 1302 of the PPACA provides for the establishment of an EHB package that includes coverage of EHB (as defined by the Secretary), cost-sharing limits, and actuarial value requirements. The law directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: Ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

Section 1301(a)(1)(B) of the PPACA directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the PPACA, including coverage of the services described in section 1302(b) of the PPACA, to adhere to the cost-sharing limits described in section 1302(c) of the PPACA and to meet the AV levels established in section 1302(d) of the PPACA. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the coverage of the EHB package to non-grandfathered individual and small group health insurance coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost sharing under the plan does not exceed the limitations described in sections 1302(c)(1) of the PPACA.

Section 1302(d) of the PPACA describes the various levels of coverage based on actuarial value (AV). Consistent with section 1302(d)(2)(A) of the PPACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the PPACA directs the Secretary to develop guidelines that allow for *de minimis* variation in AV calculations.

Section 1311(b)(1)(B) of the PPACA directs that the Small Business Health Options Program assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Sections 1312(f)(1) and (2) of the PPACA define qualified individuals and qualified employers. Under section 1312(f)(2)(B) of the PPACA, beginning in 2017, States have the option to allow issuers to offer QHPs in the large group market through an Exchange.[3] Section 1312(a)(2) of the PPACA provides that in a SHOP, a qualified employer may select a level of coverage, and that employees may then, in turn, choose SHOP plans within the level selected by the qualified employer.

[1] Before enactment of the Patient Protection and Affordable Care Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) amended the PHS Act (formerly section 2711) to generally require guaranteed availability of coverage for employers in the small group market.

[2] The implementing regulations in part 154 limit the scope of the requirements under section 2794 of the PHS Act to health insurance issuers offering health insurance coverage in the individual market or small group market. See Rate Increase Disclosure and Review; Final Rule, 76 FR 29964, 29966 (May 23, 2011).

[3] If a State elects this option, the rating rules in section 2701 of the PHS Act and its implementing regulations will apply to all coverage offered in such State's large group market (except for self-insured group health plans) pursuant to section 2701(a)(5) of the PHS Act.

Section 1311(c)(1)(B) of the PPACA requires the Secretary to establish minimum criteria for provider network adequacy that a health plan must meet to be certified as a QHP.

Section 1311(c)(5) of the PPACA requires the Secretary to continue to operate, maintain, and update the internet portal developed under section 1103 of the PPACA to provide information to consumers and small businesses on affordable health insurance coverage options.

Sections 1311(d)(4)(K) and 1311(i) of the PPACA direct all Exchanges to establish a Navigator program.

Section 1311(c)(6)(C) of the PPACA establishes special enrollment periods and section 1311(c)(6)(D) of the PPACA establishes the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.

Section 1312(e) of the PPACA directs the Secretary to establish procedures under which a State may permit agents and brokers to enroll qualified individuals and qualified employers in QHPs through an Exchange and to assist individuals in applying for financial assistance for QHPs sold through an Exchange.

Section 1321(a) of the PPACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the PPACA. Section 1321(a)(1) of the PPACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the PPACA with respect to, among other things, the establishment and operation of Exchanges.

Sections 1313 and 1321 of the PPACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1321 of the PPACA provides for State flexibility in the operation and enforcement of Exchanges and related requirements.

When operating an FFE under section 1321(c)(1) of the PPACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the PPACA to collect and spend user fees. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Office of Management and Budget (OMB) Circular A–25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

Section 1321(c)(2) of the PPACA authorizes the Secretary to enforce the Exchange standards using civil money penalties (CMPs) on the same basis as detailed in section 2723(b) of the PHS Act. Section 2723(b) of the PHS Act authorizes the Secretary to impose CMPs as a means of enforcing the individual and group market reforms contained in Part A of title XXVII of the PHS Act when a State fails to substantially enforce these provisions.

Section 1321(d) of the PPACA provides that nothing in title I of the PPACA should be construed to preempt any State law that does not prevent the application of title I of the PPACA. Section 1311(k) of the PPACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1343 of the PPACA establishes a permanent risk adjustment program to provide payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, funded by payments from those that attract lower-risk populations; thereby, reducing incentives for issuers to avoid higher-risk enrollees.

Section 1402 of the PPACA provides for, among other things, reductions in cost sharing for EHB for qualified low- and moderate-income enrollees in silver level health plans offered through the individual market Exchanges. This section also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

Section 5000A of the Code, as added by section 1501(b) of the PPACA, requires all applicable individuals to maintain minimum essential coverage (MEC) for each month or make an individual shared responsibility payment. Section 5000A(f) of the Code defines MEC as any of the following: (1) Coverage under a specified government sponsored program; (2) coverage under an eligible employer-sponsored plan; (3) coverage under a health plan offered in the individual market within a State; and (4) coverage under a grandfathered health plan. In addition, the HEALTHY KIDS Act amended section 5000A(f)(1)(A)(iii) of the Code to include in the definition of MEC CHIP look-alike plans, which are CHIP buy-in programs that provide benefits that are at least identical to the benefits provided by the title XXI CHIP program.[4] Section 5000A(f)(1)(E) of the Code authorizes the Secretary of HHS, in coordination with the Secretary of the Treasury, to designate other health benefits coverage as MEC. Under tax reform legislation that was enacted on December 22, 2017, the individual shared responsibility payment is reduced to $0, effective for months beginning after December 31, 2018.[5]

The Protecting Affordable Coverage for Employees Act (Pub. L. 114–60) amended section 1304(b) of the PPACA and section 2791(e) of the PHS Act to amend the definition of small employer in these statutes to mean, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. It also amended these statutes to make conforming changes to the definition of large employer, and to provide that a State may treat as a small employer, with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year.

1. Premium Stabilization Programs[6]

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the premium stabilization programs. We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73117), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15409).

In the December 2, 2013 **Federal Register** (78 FR 72321), we published a proposed rule outlining the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2015 Payment Notice). We published

[4] Public Law 115–120, 101 (2018).

[5] Public Law 115–97, 131 Stat. 2054.

[6] By ''premium stabilization programs,'' we are referring to the risk adjustment, risk corridors and reinsurance programs established by the PPACA.

the 2015 Payment Notice final rule in the March 11, 2014 **Federal Register** (79 FR 13743).

In the November 26, 2014 **Federal Register** (79 FR 70673), we published a proposed rule outlining the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2016 Payment Notice). We published the 2016 Payment Notice final rule in the February 27, 2015 **Federal Register** (80 FR 10749).

In the December 2, 2015 **Federal Register** (80 FR 75487), we published a proposed rule outlining the benefit and payment parameters for the 2017 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2017 Payment Notice). We published the 2017 Payment Notice final rule in the March 8, 2016 **Federal Register** (81 FR 12203).

In the September 6, 2016 **Federal Register** (81 FR 61455), we published a proposed rule outlining the benefit and payment parameters for the 2018 benefit year, and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology, new policies around the use of external data for recalibration of our risk adjustment models, and amendments to the risk adjustment data validation process (proposed 2018 Payment Notice). We published the 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058).

2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37031), we published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the ''first Program Integrity Rule'' published in the August 30, 2013 **Federal Register** (78 FR 54069) and the ''second Program Integrity Rule'' published in the October 30, 2013 **Federal Register** (78 FR 65045).

3. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to States on Exchanges on November 18, 2010. We proposed a rule in the July 15, 2011 **Federal Register** (76 FR 41865) to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) regarding Exchange functions in the individual market and SHOP, eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges was published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule).

We established additional standards for SHOP in the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541). The provisions established in the interim final rule were finalized in the second Program Integrity Rule. We also set forth standards related to Exchange user fees in the 2014 Payment Notice. We established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services Under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

In a final rule published in the July 17, 2013 **Federal Register** (78 FR 42823), we established standards for Navigators and non-Navigator assistance personnel in FFEs and for non-Navigator assistance personnel funded through an Exchange establishment grant. This final rule also established a certified application counselor program for Exchanges and set standards for that program.

In an interim final rule, published in the May 11, 2016 **Federal Register** (81 FR 29146), we made amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). We finalized these in the 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058). In the April 18, 2017 Market Stabilization final rule **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification.

4. Essential Health Benefits and Actuarial Value

On December 16, 2011, HHS released a bulletin [7] (the EHB Bulletin) that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. HHS also published a bulletin that outlined its intended regulatory approach to calculations of AV on February 24, 2012.[8] A proposed rule relating to EHBs and AVs was published in the November 26, 2012 **Federal Register** (77 FR 70643). We established requirements relating to EHBs and AVs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule). In the April 18, 2017 Market Stabilization final rule (82 FR 18346), we expanded the de minimis range applicable to plan metal levels.

5. Minimum Essential Coverage

In the February 1, 2013 **Federal Register** (78 FR 7348), we published a proposed rule that designates other health benefits coverage as MEC and outlines substantive and procedural requirements that other types of coverage must fulfill in order to be recognized as MEC. The provisions were finalized in the July 1, 2013 **Federal Register** (78 FR 39494).

In the November 26, 2014 **Federal Register** (79 FR 70674), we published a proposed rule seeking comments on whether State high risk pools should be permanently designated as MEC or whether the designation should be time-limited. In the February 27, 2015 **Federal Register** (80 FR 10750), we designated State high risk pools established on or before November 26, 2014 as MEC.

6. Market Rules

A proposed rule relating to the 2014 health insurance market rules was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing the health insurance market rules was published in the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules).

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and Beyond was published in the March 21, 2014 **Federal Register** (79 FR 15808) (2015 Market Standards Proposed Rule). A final rule implementing the Exchange and Insurance Market Standards for 2015 and Beyond was published in the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule). The 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058) provided additional guidance on guaranteed availability and

[7] ''Essential Health Benefits Bulletin.'' December 16, 2011. Available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.*

[8] ''Actuarial Value and Cost-Sharing Reductions Bulletin.'' February 24, 2012. Available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/Av-csr-bulletin.pdf.*

guaranteed renewability. In the April 18, 2017 Market Stabilization final rule (82 FR 18346), we released further guidance related to guaranteed availability.

7. Rate Review

A proposed rule to establish the rate review program was published in the December 23, 2010 **Federal Register** (75 FR 81003). A final rule with comment period implementing the rate review program was published in the May 23, 2011 **Federal Register** (76 FR 29963) (Rate Review Rule). The provisions of the Rate Review Rule were amended in final rules published in the September 6, 2011 **Federal Register** (76 FR 54969), the February 27, 2013 **Federal Register** (78 FR 13405), the May 27, 2014 **Federal Register** (79 FR 30239), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203) and the December 22, 2016 **Federal Register** (81 FR 94058).

8. Medical Loss Ratio

We published a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75 FR 74863). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790). The medical loss ratio program requirements were amended in final rules published in the March 11, 2014 **Federal Register** (79 FR 13743), the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), and the December 22, 2016 **Federal Register** (81 FR 94183).

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges, including the SHOP, and the premium stabilization programs. We have held a number of listening sessions with consumers, providers, employers, health plans, and the actuarial community to gather public input. We have solicited input from State representatives on numerous topics, particularly EHB, QHP certification and Exchange establishment. We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with States through the Exchange Establishment grant and Exchange Blueprint approval processes, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all public input we received as we developed the policies in this final rule.

HHS also received several thousand unique comments in response to a request for information, entitled ''Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act and Improving Healthcare Choices to Empower Patients'', published in the June 12, 2017 **Federal Register** (82 FR 26885) (Request for Information). We anticipate continuing to address comments in future rulemaking and guidance.

C. Structure of Final Rule

The regulations outlined in this final rule will be codified in 45 CFR parts 147, 153, 154, 155, 156, 157, and 158.

The final regulations in part 147 amend the rules regarding fair health insurance premiums and guaranteed availability to reflect final changes related to the SHOPs and special enrollment periods.

In connection with part 153, we are recalibrating the risk adjustment models consistent with the methodology finalized for the 2018 benefit year with slight modifications to the drug classes included in the 2019 benefit year adult models and the incorporation of blended MarketScan® and the most recent enrollee-level External Data Gathering Environment (EDGE) data. This final rule addresses the high-cost risk pooling adjustment, where we are finalizing the same parameters that applied to the 2018 benefit year for the 2019 benefit year risk adjustment. The finalized provisions related to part 153 include the risk adjustment user fee and modifications to risk adjustment data validation. We also finalize a policy to provide States flexibility to request reductions in risk adjustment transfers in the small group market starting for the 2020 benefit year and beyond.

The final regulations in part 154 finalize certain modifications to reduce regulatory burden and enhance State flexibility for the rate review program. We are finalizing an exemption for student health insurance coverage from Federal rate review requirements. We are finalizing a proposal to raise the default threshold for review of reasonableness in the rate review process from 10 percent to 15 percent. We also are finalizing a proposal to allow States with Effective Rate Review Programs to set later submission deadlines for rate filings from issuers that offer non-QHPs only. In addition, we are finalizing the change to the notification period for States with Effective Rate Review Programs to provide advance notice to HHS prior to posting rate increases (from 30 days to 5 business days).

The final regulations in part 155 include modifications to the functions of an Exchange, and a new approach to operational readiness reviews for direct enrollment partners which will allow agents, brokers, and issuers to select their own third-party entities for conducting those reviews. We are finalizing modifications to the rules around verification of eligibility. We are also finalizing increased flexibility in the Navigator program by removing the requirement that each Exchange must have at least two Navigator entities, one of which must be a community and consumer focused non-profit, and by removing the standard requiring physical presence of the Navigator entity in the Exchange service area. We are modifying the parameters around certain special enrollment periods. We are modifying the effective date options for enrollee-initiated terminations, at the option of the Exchange, and amending the affordability exemption so that it may be based on the lowest cost Exchange plan if there is no bronze level plan sold through the Exchange in that rating area.

The final regulations in part 156 include changes to EHB and the QHP certification process. The final regulations in part 156 set forth parameters related to cost sharing, including the premium adjustment percentage, the maximum annual limitation on cost sharing, and the reductions in the maximum annual limitation for cost-sharing plan variations for 2019. The regulations at part 156 also include finalized FFE and SBE–FP user fee rates for the 2019 benefit year for all issuers participating on the FFEs or SBE–FPs. The regulations at part 156 also include finalized policies related to actuarial value for stand-alone dental plans (SADPs).

The final amendments to the regulations in parts 155, 156, and 157 include finalized proposals that would provide SHOPs with additional operational flexibility, and would modify the requirements for issuers, employers, and employees interacting with SHOPs.

The final amendments to the regulations in part 158 include revisions related to reporting quality improvement activity expenses as part

of the formula for calculating MLR, and revisions related to State requests for adjustment to the individual market MLR standard.

III. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

In the November 2, 2017 **Federal Register** (82 FR 51052), we published the ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019'' proposed rule (proposed 2019 Payment Notice or proposed rule). We received 416 comments, including 99 comments that were substantially similar to one of four different letters, each regarding the proposals on EHBs, one addressing EHBs and the Navigator program, and one addressing proposals related to EHBs, Navigators, SHOPs and network adequacy. Comments were received from State entities, such as departments of insurance and State Exchanges; health insurance issuers; providers, both individuals and provider groups; consumer groups; industry groups; national interest groups; and other stakeholders. The comments ranged from general support of or opposition to the proposed provisions to specific questions or comments regarding proposed changes. We received a number of comments and suggestions that were outside the scope of the proposed rule that will not be addressed in this final rule.

In this final rule, we provide a summary of each proposed provision, a summary of those public comments received that directly related to the proposals, our responses to them, and a description of the provisions we are finalizing.

Comment: We received multiple comments criticizing the short comment period, stating that the comment period made it difficult for stakeholders to conduct an in-depth analysis of the proposed rule. Commenters suggested that HHS adopt a comment period of at least 30 days from rule publication, and to fully comply with notice-and-comment requirements under the Administrative Procedure Act.

Response: The timeline for publication of this final rule accommodates issuer filing deadlines for the 2019 benefit year. A longer comment period would have delayed the publication of this final rule, and created significant challenges for States, Exchanges, issuers, and other entities in meeting deadlines related to implementing these rules. We will continue to try to expand the comment period for the annual HHS notice of benefit and payment parameters while also providing industry and other stakeholders with more time to implement the final rule.

Comment: We received some comments generally supportive of State flexibility, stating that by removing existing regulatory barriers, issuers will be able to offer a more diverse selection of coverage options that meet both the financial and health coverage needs of consumers while meeting various State needs.

Response: We agree that State flexibility with respect to oversight of State insurance markets is an important goal, and recognize the traditional role States have as the primary regulators of their insurance markets. States are best positioned to address the specific needs of their consumers, and may be better able than the Federal government to develop policies that are tailored to allow issuers in their State to develop plans that address both the needs and cost concerns of beneficiaries in their State.

Comment: We received numerous comments cautioning us about making changes that would weaken the PPACA. Some commenters expressed concern that the proposed changes would remove some of the protections afforded by the PPACA, such as the certainty of EHBs.

Response: Our top priority at HHS is putting consumers first. While we have made great strides forward, there is still work to be done, including ensuring that coverage is affordable to all consumers. We have already taken important steps to streamline our regulations and our operations with the goal of reducing unnecessary burden, increasing efficiencies and improving the consumer experience. Yet, we have recently seen how regulations intended to protect consumers can, instead, undermine consumers' access to affordable health coverage. In this final rule, we finalize policies that are intended to help control costs of coverage in order to make coverage more affordable for consumers, particularly unsubsidized consumers. We will continue to find innovative ways to reduce costs and burdens while meeting the health needs of all Americans. We are continuing to address feedback we receive from stakeholders and the public, and in turn we are making changes that will better serve consumers and allow States to address the unique health needs of their populations.

Comment: Commenters responded to our request for comment on ideas for future rulemaking about ways to help reduce drug costs and promote drug price transparency. All commenters acknowledged the consumer benefits of lowering drug costs and having more transparent drug pricing; however, commenters cautioned that any changes be done in a thoughtful manner, that considers value in addition to cost, with input from all stakeholders.

Response: We appreciate the ideas for future rulemaking and will consider these suggestions.

A. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Fair Health Insurance Premiums (§ 147.102)

As discussed elsewhere in this final rule, we are finalizing substantial changes to the requirements applicable to SHOPs to provide those programs with the flexibility to operate in a leaner fashion, a flexibility that we intend to utilize in the Federally-facilitated Small Business Health Options Program (FF–SHOP). As part of these changes and, as discussed in the preamble to §§ 156.285 and 156.286, we proposed that, effective on the effective date of this rule, the requirement in § 156.285(a)(4)(ii) regarding premium rating standards in the FF–SHOPs would not apply for plan years beginning on or after January 1, 2018. Therefore, we proposed to delete from § 147.102(c)(3)(iii)(D) a reference to § 156.285(a)(4), and to replace the reference to FF–SHOPs with a reference to SHOPs generally, to reflect that, under the proposed approach for SHOPs, some SHOPs may want to prohibit issuers from offering average enrollee premiums.

We did not receive comments on this proposal, and are finalizing the change as proposed, with one minor typographical correction.

We also sought comment on whether issuers offering coverage through SHOPs should always be required to offer average enrollee premiums, or should be required to do so only if required under applicable State law.

Comment: Comments were mixed regarding whether issuers offering coverage through SHOPs should always be required to offer average enrollee premiums. One commenter stated that issuers offering coverage through SHOPs should always be required to offer average enrollee premiums, while others stated that issuers should be required to do so only if required by applicable State law. One of these commenters further recommended that average premium rating should be permitted only when a SHOP does not allow employees to choose plans among multiple issuers. The commenter stated that average enrollee premiums based

on employees selecting a particular plan could result in illogical rates, such as a richer plan having lower rates than a leaner plan because only younger employees selected the richer plan. Another commenter stated that all issuers, regardless of whether they are offering coverage on or off SHOP, should be allowed to offer average enrollee premiums.

Response: For purposes of consistency, we believe that issuers offering coverage through a SHOP should be permitted to offer average enrollee premiums to the same extent that issuers may do so off SHOP under existing State rules. Also, given the decrease in issuer participation in the FF–SHOPs, some SHOP employers only have one issuer offering FF–SHOP plans in their area and will not be able to offer their employers a choice of plans across issuers. In addition, historically, a majority of employers have not offered employee choice across different issuers, thus mitigating the risk of variance in average premium rates across plans. Therefore, we do not believe Federal guidance or regulation is currently warranted in this area. Thus, issuers offering coverage through a SHOP may offer average enrollee premiums to the extent required or permitted by the applicable State, and will not be required under Federal law to do so, unless required by the State.

2. Guaranteed Availability of Coverage (§ 147.104)

i. SHOP

As discussed elsewhere in this final rule, we proposed and are finalizing substantial changes to the requirements applicable to SHOPs to provide them with the flexibility to operate in a leaner fashion, a flexibility that we will utilize in the FF–SHOPs. Among those changes, effective on the effective date of this rule, the requirements in § 156.285 will apply for plan years starting before January 1, 2018. New § 156.286 specifies those requirements contained in § 156.285 that, effective on the effective date of this rule, will continue to apply for plan years starting on or after January 1, 2018. Among those requirements is the requirement in § 156.285(e) which permits a QHP offered in the SHOP to apply group participation rules under certain circumstances. This provision will be listed in new § 156.286(e). The marketwide regulations at § 147.104(b)(1)(i)(B) currently reference § 156.285(e), and we proposed to add a reference to § 156.286(e) to clarify that, effective on the effective date of this rule, for plan years that start on or after January 1, 2018, QHPs offered in the SHOP may restrict the availability of coverage, with respect to a group health plan that cannot comply with group participation rules, to an annual enrollment period of November 15 through December 15 of each calendar year. Because we are finalizing new § 156.286(e) as proposed, we are also finalizing the proposal to reference new § 156.286(e) in § 147.104(b)(1)(i)(B).

Comment: One commenter supported the proposal to add to § 147.104(b)(1)(i)(B) a reference to § 156.286(e). One commenter opposed permitting QHPs to restrict coverage availability when a group health plan cannot comply with group participation rules, while another commenter stated that an employer that fails to comply with such rules should not be afforded guaranteed availability of coverage, either generally or during an annual open enrollment period, either on or off-SHOP.

Response: As indicated in the section of the preamble discussing the SHOP rule, we are finalizing, as proposed, the proposal to add new § 156.286(e), which would apply, to plan years starting on or after January 1, 2018, the existing regulatory provision that allows QHPs offered in the SHOP to restrict the availability of coverage with respect to a group health plan that cannot comply with group participation rules, to an annual enrollment period of November 15 through December 15 of each calendar year. Thus, we are also finalizing the proposal to reference new § 156.286(e) in § 147.104(b)(1)(i)(B).

We also proposed, and are finalizing, the removal of the small group coverage effective dates that are found in the SHOP regulations at § 155.725 with respect to plan years beginning on or after January 1, 2018, effective on the effective date of this rule. However, there are currently requirements in § 147.104(b)(1)(i)(C) that, by cross-referencing § 155.725, apply those same requirements marketwide, and we did not propose to remove that marketwide requirement. We proposed changes to § 147.104 to reflect the SHOP changes. Specifically, we proposed to eliminate, from § 147.104(b)(1)(i)(C), the cross-reference to § 155.725. We proposed in place of the cross-reference to explicitly specify in § 147.104(b)(1)(i)(C) those same coverage effective dates for coverage in the small group market, and for the large group market if such coverage is offered through a SHOP, that would be eliminated from the SHOP regulations under our proposal for § 155.725. We are finalizing this proposal, but are modifying the language that will replace the cross-reference to clarify that it is permissible for issuers to apply an effective date of coverage that is *before* or on the specified dates. We are also modifying the proposed language so that the effective date of coverage is tied to the date a group enrollment is received, rather than to the date a plan selection is received.

Comment: All commenters supported in principle the proposal to eliminate, from § 147.104(b)(1)(i)(C), the cross reference to the effective dates of coverage in § 155.725, and in its place explicitly specify in § 147.104(b)(1)(i)(C) those effective dates for coverage in the small group market, and for the large group market if such coverage is offered through a SHOP. However, several commenters noted that our proposal did not import the provisions in § 155.725, describing the coverage effective dates, verbatim into § 147.104(b)(1)(i)(C). They observed that the proposed language in § 147.104(b)(1)(i)(C) tied the coverage effective date to the date a plan selection was received, rather than to the date a group enrollment was received, and that tying the coverage date to the date a group enrollment was received (as in the effective-date-of-coverage language currently set forth in § 155.725) would be more appropriate. Commenters also stated that the language we proposed to add in § 147.104(b)(1)(i)(C), unlike the language in current regulations in § 155.725, would prohibit issuers from applying a coverage effective date that falls *before* the first day of the following month, or *before* the first day of the second following month, as applicable, after the date a group enrollment is received.

Response: As commenters pointed out, in the language we proposed for § 147.104(b)(1)(i)(C), we tied the coverage effective date to the date a plan selection, rather than a group enrollment, was received. Given that the proposed language we added appears in a section of the rules (§ 147.104) that applies marketwide, and not just in SHOPs, we agree with the commenters that tying the coverage date to a group enrollment, which is a broader term than a plan selection (the latter is a SHOP-specific term), would be more appropriate. We also agree with the commenters that the existing language in § 155.725, which requires issuers to ensure a coverage effective date *of,* rather than *on,* the dates specified in the existing language, permits issuers to apply an enrollment date that falls *before,* rather than only *on,* the first day of the first month or the first day of the second month (as applicable) following the date a group enrollment is received, and that issuers should continue to have

the flexibility to apply an enrollment date that falls *before* those dates. Therefore, in light of those comments, we are finalizing language in § 147.104(b)(1)(i)(C).

ii. Special Enrollment Periods

Section 147.104(b)(2)(i) extends several of the special enrollment periods that apply to issuers on the Exchange, to all issuers in the individual market. Although § 147.104(b)(2)(i) is intended to specify which special enrollment periods offered through the Exchange must also be offered by health insurance issuers with respect to coverage offered outside of an Exchange, the paragraph as currently written could be read to apply the exceptions to any coverage offered by a health insurance issuer in the individual market. We recognize the potential for confusion, as coverage offered through an Exchange is offered by a health insurance issuer in the individual market, but this coverage is subject to the special enrollment rule at § 155.420(d), which is intended to require special enrollment periods for qualifying events including those listed in the exceptions in § 147.104(b)(2)(i). Therefore, we proposed to amend that phrase in § 147.104(b)(2)(i) to clarify that the exceptions in the paragraph only apply with respect to coverage offered outside of the Exchange in the individual market. We received no comments on this proposal, and are finalizing it as proposed.

With respect to the subset of special enrollment periods in § 155.420 that apply off-Exchange, current regulations at § 147.104(b)(2)(ii) state that, in applying § 147.104(b)(2), a reference in § 155.420 to a ''QHP'' is deemed to refer to a plan, a reference to ''the Exchange'' is deemed to refer to the applicable State authority, and a reference to a ''qualified individual'' is deemed to refer to an individual in the individual market. As discussed in the preamble to § 155.420, we are finalizing a change to § 155.420(a)(5) to exempt qualified individuals from the prior coverage requirement that applies to certain special enrollment periods if they lived in a service area where no qualified health plan was available through the Exchange for 1 or more days during the 60 days preceding the qualifying event or during their most recent preceding enrollment period, as specified in §§ 155.410 and 155.420. Section 155.420(a)(5) applies to qualifying individuals seeking off-Exchange coverage through an applicable special enrollment period, so we proposed that this exception for individuals living in a service area where there were no QHPs offered through an Exchange would also apply.[9] However, in this instance the reference to ''QHP'' should not be deemed to refer to a plan for purposes of applying § 147.104(b)(2). Therefore, we proposed to amend § 147.104(b)(2)(ii) to state that a reference in § 155.420 (other than in § 155.420(a)(5)) to a ''QHP'' is deemed to refer to a plan, a reference to ''the Exchange'' is deemed to refer to the applicable State authority, and a reference to a ''qualified individual'' is deemed to refer to an individual in the individual market. We are finalizing this change as proposed.

Comment: All commenters supported this proposal, while some commenters stated more generally that special enrollment periods should be the same, regardless of whether an individual is seeking coverage on or off-Exchange. One commenter suggested that we publish a list of bare counties so that the exemption to the prior-coverage requirement can be properly applied both on and off-Exchange.

Response: We are finalizing the proposal, consistent with the way in which the amendment to § 155.420(a)(5) is being finalized, and if there are ever any service areas in which no qualified health plans are offered through the Exchange, we will consider publishing a list of them, as the commenter suggested. For a more detailed response to comments regarding the amendment to § 155.420(a)(5), see the preamble to that section.

Among the special enrollment periods in § 155.420 that apply off-Exchange are those specified in § 155.420(d)(2)(i), under which a qualified individual gains a dependent or becomes a new dependent through marriage, birth, adoption, placement for adoption, or placement in foster care, or through a child support order or other court order. We sought comment on whether this special enrollment period should afford an individual's existing dependents an independent opportunity to enroll, off-Exchange, in new coverage or make changes to their existing coverage. As applied to on-Exchange coverage, when a qualified individual gains or becomes a new dependent under the circumstances described in § 155.420(d)(2)(i), the qualified individual is afforded a special enrollment period to enroll in or change Exchange coverage with his or her dependents, including his or her newly-gained dependent, in accordance with any applicable metal level restrictions outlined in § 155.420(a)(4)(i). The new dependent is also afforded an independent special enrollment period under which he or she can enroll in or change Exchange coverage as a subscriber, as opposed to as a dependent of the qualified individual. Under the HIPAA special enrollment provisions that continue to apply to group health plans and health insurance issuers in connection with group health coverage, there are similar special enrollment periods when a child becomes a dependent of the employee through marriage, birth, adoption, or placement for adoption.[10] We sought comment on whether, in the off-Exchange individual market, the special enrollment periods for when an individual gains a dependent or becomes a new dependent under the circumstances described in § 147.104(b)(2), which cross-references § 155.420(d)(2)(i), should continue to operate in the same manner as they do on-Exchange, whether they should operate in a manner consistent with the HIPAA group market regulations, or whether we should adopt some other approach.

With respect to off-Exchange coverage, we are maintaining current policy under which an individual who qualifies for a special enrollment period for gaining a dependent through marriage, birth, adoption, placement for adoption, or placement in foster care, or through a child support order or other court order under § 147.104(b)(2) may enroll in or change coverage along with his or her dependents, including the newly-gained dependent(s) and any existing dependents. The new dependent is also afforded an independent special enrollment period under which he or she can enroll in or change coverage as a subscriber, as opposed to as a dependent of the

[9] As stated in the preamble in the proposed rule to § 155.420, the exception to the requirement to have previous coverage is intended to relieve individuals of that requirement when there was no *affordable* coverage (that is, coverage that could be purchased through an Exchange to which APTC might apply) available in their previous service area. We believe affordability is key to this exception, and therefore, that the scope of the exception should apply equally, regardless of whether the individual is seeking to purchase coverage inside *or* outside an Exchange during the special enrollment periods for which this exception applies; that is, the exception should apply if there was no such affordable coverage available in the individual's previous service area (regardless of whether or not any coverage was being actively marketed in that service area outside the Exchange). Also, when an individual sought to purchase coverage outside an Exchange during such a special enrollment period, we believe it might be unreasonably difficult for an issuer to determine if at least one issuer was actively marketing coverage in the individual's previous service area outside the Exchange, as opposed to determining if at least one issuer was making coverage available in that service area specifically through an Exchange. We solicited comments on this approach.

[10] See § 146.117(b).

individual. This off-Exchange special enrollment period does not otherwise provide to existing dependents an independent opportunity to enroll in new coverage or make changes to their existing coverage.

Comment: Some commenters stated that existing dependents should be entitled to enroll with other family members who have qualified for the special enrollment period when a qualified individual in their household gains a dependent or becomes a new dependent through marriage, birth, adoption, placement for adoption, or placement in foster care, or through a child support order or other court order, while others believed they should not, stating that allowing this practice would contribute to adverse selection. Some commenters stated that special enrollment periods should apply uniformly on-Exchange and off-Exchange.

Response: As stated previously, we are continuing to apply the parameters of the special enrollment period for those who have gained or become a new dependent through marriage, birth, adoption, foster care placement, or a child support or other court order off-Exchange in the same manner as applied on-Exchange. We believe the advantages and simplicity of uniformity between on-Exchange and off-Exchange coverage in this instance outweigh the concern about adverse selection.

iii. Technical Changes

We proposed to remove paragraph § 147.104(b)(1)(iii), along with the cross-reference to it in § 147.104(b)(1)(ii), as paragraph (b)(1)(iii) applies to plan selections made in 2013, and is therefore no longer necessary. We received no comments regarding this proposal, and are finalizing these changes as proposed.

B. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Under the Affordable Care Act

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2018,[11] both the transitional reinsurance program and permanent risk adjustment program are subject to the fiscal year 2018 sequestration. The Federal government's 2018 fiscal year began October 1, 2017. Although the 2016 benefit year was the final year of the transitional reinsurance program, HHS will continue to make reinsurance payments in the 2018 fiscal year, as the second contribution collection deadline for the 2016 benefit year was November 15, 2017. Therefore, the reinsurance program will be sequestered at a rate of 6.6 percent for payments made from fiscal year 2018 resources (that is, funds collected during the 2018 fiscal year). The risk adjustment program will also be sequestered at a rate of 6.6 percent for payments made from fiscal year 2018 resources (that is, funds collected during the 2018 fiscal year).

HHS, in coordination with the OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended, and the underlying authority for the reinsurance and risk adjustment programs, the funds that are sequestered in fiscal year 2018 from the reinsurance and risk adjustment programs will become available for payment to issuers in fiscal year 2019 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, these programs would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

2. Provisions and Parameters for the Risk Adjustment Program

In subparts D and G of part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the PPACA that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. In accordance with § 153.310(a), a State that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. Beginning with the 2017 benefit year, HHS is operating risk adjustment in every State, and did not receive any applications from States to operate risk adjustment for the 2019 benefit year.

a. Overview of the HHS Risk Adjustment Model (§ 153.320)

The HHS risk adjustment model predicts plan liability for an average enrollee based on that person's age, sex, and diagnoses (risk factors), producing a risk score. The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for cost differences in each of these age groups. In each of the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, in the adult models, we added enrollment duration factors beginning for the 2017 benefit year, and prescription drug utilization factors (RXCs) beginning for the 2018 benefit year, in the calculation of enrollees' risk scores. Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children or infants is multiplied by a cost-sharing reductions adjustment.

The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan (also referred to as the plan liability risk score) within a geographic rating area is one of the inputs into the risk adjustment payment transfer formula, which determines the payment or charge that an issuer will receive or be required to pay for that plan. Thus, the HHS risk adjustment model predicts average group costs to account for risk across plans, which accords with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

b. Final Updates to the Risk Adjustment Model (§ 153.320)

For the 2019 benefit year, we proposed to recalibrate the risk adjustment models using the methodology finalized for the 2018 benefit year, with small modifications to the drug classes included in the 2019 benefit year adult models, and incorporation of the 2016 benefit year enrollee-level EDGE data in the 2019 benefit year risk adjustment model recalibration.

i. Recalibration Using EDGE Data

To recalibrate the 2016, 2017 and 2018 benefit year risk adjustment models, we used the 3 most recent years of Truven MarketScan® data. This approach allowed for using the blended, or averaged, coefficients from 3 years of separately solved models, which promotes stability for the risk adjustment coefficients year-to-year, particularly for rare conditions with small sample sizes. We finalized in the 2018 Payment Notice the collection of enrollee-level EDGE data and the recalibration of the risk adjustment model for the 2019 benefit year using 2016 benefit year EDGE data. We believe that blending the coefficients calculated from the 2016 benefit year enrollee-level EDGE data with MarketScan® data will provide stability within the risk

[11] Available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/sequestration_reports/2018_jc_sequestration_report_may2017_potus.pdf.*

adjustment program and minimize volatility in changes to risk scores from the 2018 to 2019 benefit years due to differences in the datasets' underlying populations. As such, we proposed blending 3 years of data to recalibrate the coefficients used in the risk adjustment models and, for the 2019 benefit year, blending separately solved coefficients from the 2016 benefit year enrollee-level EDGE data and the 2014 and 2015 MarketScan® data.

Given the timing of the proposed rule, we were not able to incorporate the 2016 benefit year enrollee-level EDGE data in the proposed rule. Instead, we used the 2014 and 2015 MarketScan® data for the coefficients displayed in the proposed rule. We proposed to finalize the 2019 benefit year blended coefficients with the separately solved models from the 2016 benefit year enrollee-level EDGE data, and the 2014 and 2015 MarketScan® data. This is similar to our approach in previous years, in which we updated the final coefficients using data from the most recently available benefit year.[12] We explained that we expected to publish the final risk adjustment model coefficients for the 2019 benefit year in the final rule. However, we sought comment on whether we should publish the final risk adjustment model coefficients in guidance in the spring of 2018, prior to rate setting for the 2019 benefit year, if we needed additional time to analyze the 2016 enrollee-level EDGE data. Under either approach, we proposed that the final risk adjustment model coefficients for the 2019 benefit year would be determined using the methodology that we would finalize in this rule, and would be published prior to the 2019 benefit year rate setting. Additionally, if we found significant demographic or distributional differences in the enrollee-level EDGE data compared to the MarketScan® data, we sought comment on whether we should make adjustments to the risk adjustment recalibration model age-sex, hierarchical condition categories (HCCs), and RXC categories for the 2019 benefit year. In such a case, we proposed we would make adjustments to the models to better align them with the enrollee-level EDGE data, to improve the prediction of plan liability.

We sought comment on our proposal to determine coefficients based on a blend of 2014 and 2015 MarketScan® data and 2016 enrollee-level EDGE data. We also sought comment on the proposed methodology to equally weight the separately solved model coefficients from the 2014 MarketScan®, 2015 MarketScan®, and 2016 enrollee-level EDGE data for the final coefficients, instead of using only the 2016 enrollee-level EDGE data to recalibrate the risk adjustment model coefficients for the 2019 benefit year.

We are finalizing the approach using equally blended coefficients from separately solved 2014 MarketScan®, 2015 MarketScan®, and 2016 enrollee-level EDGE data to recalibrate the risk adjustment model coefficients for the 2019 benefit year. We are not making any changes to age-sex or HCC categories, because we did not find significant distributional differences, and we will continue to assess whether to propose any specific changes to the categories for future benefit years in future rulemaking. We did not propose and are not making any changes to the enrollment duration categories. Please see the preamble section below on ''Prescription Drugs'' for a discussion of changes being finalized with respect to the RXC categories. The final risk adjustment model coefficients for the 2019 benefit year risk adjustment program are listed in Tables 2, 4 and 5 of this rule.

Comment: Commenters supported the use of enrollee-level EDGE data in model recalibration noting the data would more closely reflect the relative risk differences of individuals in the individual and small group markets compared to the MarketScan® data. Most commenters also supported equally blending coefficients from separately solved models using 3 years of data to promote stability year over year, thereby phasing in the use of enrollee-level EDGE data. A few commenters supported overweighting the 2016 enrollee-level EDGE data, with one commenter supporting overweighting of the 2016 data if sample sizes are adequate. A few commenters supported using only the 2016 enrollee-level EDGE data for recalibration, stating that MarketScan® data will have different utilization and risk patterns, and socioeconomic status for enrollees with employer-based coverage than the EDGE data, which directly reflects PPACA individual and small group market enrollees. These commenters also stated that these differences in the underlying data could cause the risk adjustment coefficients to over- or under-predict risk differences. One commenter stated that relying on older data to calibrate the model could lead to significant gaps in the risk adjustment methodology. One commenter requested clarification as to the volatility in changes to risk scores from the 2018 to 2019 benefit years that could occur due to differences in the datasets' underlying populations. Another commenter requested that recalibration using EDGE data be postponed until all States' data is available in the 2017 benefit year.[13] Some commenters requested separate publication of the coefficients from the 2016 enrollee-level EDGE data. One commenter requested clarification as to what weights would be applied in blending coefficients from the 3 years of data. Most commenters also supported HHS finalizing the 2019 benefit year coefficients prior to rate setting in guidance, while a few others requested the coefficients be finalized in the final rule. One commenter noted that delaying publication of the final coefficients past the publication of the final rule would pose challenges in issuers' rate setting timelines, while some commenters suggested that if HHS needs additional time beyond the publication of the final rule, the final coefficients for the 2019 benefit year should be published no later than February 28, 2018.

Response: For small sample sizes, year-to-year differences in spending due to data anomalies can cause significant differences in a particular solved coefficient. We agree that blending coefficients from multiple years of data can provide stability in changes in the recalibrated model coefficients and provide certainty to issuers, particularly where small sample sizes could lead to volatility in the solved coefficients from year-to-year. Additionally, while there are differences in total spending in MarketScan® compared to enrollee-level EDGE data, we have found that the relative risk differences for age-sex, HCC and RXC categories are generally similar to those in the MarketScan® data, and therefore, do not believe that blending the data will cause significant over- or under-prediction of relative risk scores on average. Enrollee-level EDGE data shows lower spending and relative risk patterns for shorter enrollment durations compared to the MarketScan® data, resulting in smaller enrollment duration coefficients for all 11 months. This result was expected, given that enrollees in large group coverage have longer enrollment duration and a higher proportion of individuals with a full-year of enrollment on average than enrollees in the individual and small group markets, and that the greater number of shorter average enrollment durations in the enrollee-level EDGE

[12] See, for example, 2018 Payment Notice, 81 FR 94058 (December 22, 2016).

[13] Massachusetts is not included in the 2016 benefit year enrollee-level EDGE data, because Massachusetts operated its own risk adjustment program through the 2016 benefit year.

data account for lower relative risk on average.

Additionally, while Massachusetts is not included in the 2016 benefit year enrollee-level EDGE data, the relative risk differences for enrollees in Massachusetts are likely similar on average to those for enrollees in other States. The 2017 benefit year enrollee-level risk EDGE data will not be available until the end of summer 2018, after the 2019 benefit year risk adjustment factors need to be published to support 2019 benefit year benefit design and rate development, and therefore cannot be used for this recalibration effort. We believe that a national dataset of individual and small group market claims experience for the most recent benefit year is the preferable data source—even without the incorporation of one State—compared to only using commercial claims data for risk adjustment model recalibration and risk estimation in the individual and small group markets.

In all, we believe blending the coefficients promotes stability and certainty for issuers in rate setting, smoothing any significant differences as with the EDGE enrollment duration factors, while maintaining the relative average risk differences stakeholders have expected from the MarketScan®-only coefficients. Therefore, we are finalizing our proposal to equally weight coefficients from separately solved models using 2014 MarketScan®, 2015 MarketScan®, and 2016 enrollee-level EDGE data for the final 2019 benefit year risk adjustment model recalibration. We also were able to complete our analysis of the 2016 EDGE data in time to publish the final coefficients blended with 2016 enrollee-level EDGE data in this final rule. The final 2019 benefit year risk adjustment model coefficients listed in Tables 2, 4, and 5 are blended coefficients using equally weighted coefficients solved from the 2014 MarketScan®, 2015 MarketScan®, and 2016 enrollee-level EDGE data.

Comment: Commenters requested clarification on the analytical dataset development process using the 2016 enrollee-level EDGE data, sample size of the enrollee-level EDGE data, and differences in EDGE and MarketScan® data.

Response: We arrived at the 2016 enrollee-level EDGE analytical dataset using several criteria. We limited the sample to ages 0–64 to maintain the same age categories as those HHS has used in the MarketScan® data, with which the EDGE coefficients are blended. Currently, we use the age 60–64 factors for those over 65 years of age enrolled in individual and small group market coverage, and will continue to do so for the 2019 benefit year. We will consider whether to propose expanding the age and sex factors to include age groups and associated costs for enrollees ages 65 and above in future model recalibrations. We also excluded derived claims, any newborn diagnoses for infants older than one year of age, anomalous claims (for example, pregnancy diagnoses if sex is male) and those with sex unknown. There were approximately 47 million, 28 million and 31 million total unique enrollees in the 2014 MarketScan®, 2015 MarketScan®, and 2016 enrollee-level EDGE data, respectively. Relative risks were similar in the 2016 enrollee-level EDGE data for most categories in all three adult, infant and child samples. As mentioned above, enrollee-level EDGE data reflected lower spending and relative risk patterns for shorter enrollment duration enrollees compared to MarketScan® data.

Comment: In case of significant demographic or distributional differences in the EDGE data compared to the MarketScan® data, most commenters supported HHS making adjustments to give greater weight to the EDGE data when recalibrating the model coefficients. However, commenters did not support making changes to the age-sex, HCC, enrollment duration or RXC factors categorizations beyond what was in the proposed rule, and instead supported such changes to be implemented for the 2020 benefit year.

Response: We did not identify significant differences in the relative risk for enrollees over 65 compared to those in the 60–64 age group in the enrollee-level EDGE data compared to the MarketScan® data, and therefore, are finalizing the risk adjustment model categories as proposed. As noted above, we will continue to assess relative differences in demographic and spending patterns in the EDGE data and will consider amending the risk adjustment model categories in future recalibrations, particularly once we have multiple years of enrollee-level EDGE data.

Comment: A few commenters requested that HHS limit the scope of enrollee-level EDGE data collection and use, clarify the types of data elements collected in the enrollee-level EDGE data, proceed with caution given the data privacy and trade secret information, and prohibit any other use of the data.

Response: These comments are outside the scope of the proposed rule. As finalized in the 2018 Payment Notice, HHS is collecting enrollee-level EDGE data, which provides more granular claims data from the individual and small group markets, and is being used to improve the recalibration of HHS programs. Additionally, as noted in the 2018 Payment Notice, HHS recognizes the sensitivity of enrollee-level EDGE data, and is not collecting masked enrollee IDs from issuers' EDGE servers, plan or issuer IDs, rating areas, or State data elements to safeguard the privacy and security of protected health information (PHI) and minimize potential risks to issuers' proprietary information.

ii. Prescription Drugs

In the 2018 Payment Notice, we finalized the inclusion of 12 RXCs that interact with HCCs, or drug-diagnosis (RXC–HCC) pairs, in the adult risk adjustment models for the 2018 benefit year. Ten of the RXC–HCC pairs have three levels of incremental predicted costs (diagnosis-only, prescription drug-only, and both diagnosis and prescription drug), indicating that they can be used to impute a particular diagnosis. The 2018 benefit year risk adjustment adult models also included two RXC–HCC pairs that are used for severity-only—that is, they predict incremental costs for enrollees with the diagnosis-only, or with both the diagnosis and the prescription drug. For enrollees without the associated diagnoses documented for these severity-only RXC–HCC pairs, the presence of the drug alone would not lead to the attribution of additional plan liability costs to the plan.

For the 2019 benefit year, we proposed to remove the two severity-only RXCs (RXC 11: Ammonia Detoxicants, and RXC 12: Diuretics, Loop and Select Potassium-Sparing). Both have low average costs per enrollee per year and were constrained in the 2018 benefit year adult risk adjustment models final coefficients to the average cost of the drugs to avoid overcompensating issuers for these RXCs. Constraining these RXCs removed overprescribing and gaming incentives to prescribe a low-cost drug to receive a much larger risk adjustment payment. However, after constraints, these two severity-only RXCs have extremely small coefficients that no longer predict meaningful incremental plan risk associated with a severe health condition. Therefore, we proposed eliminating these two RXCs from the adult models beginning with the 2019 benefit year. As explained in the proposed rule, we believe the remaining RXCs do not engender significant gaming concerns due to the cost and side-effects of the drugs if prescribed

without cause. As we noted in the 2018 Payment Notice, where the risk of unintended effects on provider prescribing behavior is low, we will continue to include a small number of prescription drug classes as predictors of risk and plan liability. For the remaining RXCs, we explained there is a high rate of presence of a diagnosis code in the associated HCC in the MarketScan® data, indicating a positive predictive value for using these RXCs to impute missing diagnoses. Additionally, we noted that we intend to monitor prescription drug utilization for unintended effects, and may propose to remove drug classes based on such evidence in future rulemaking. We are finalizing the removal of RXC11 and RXC12 from the adult risk adjustment models beginning with the 2019 benefit year. Table 1 contains the final list of prescription drug factors included in the 2019 benefit year risk adjustment adult models. We will continue to evaluate the effects of incorporating prescription drugs in the adult models to determine whether to continue, broaden or reduce the impact of this set of factors.

Comment: Most commenters supported the removal of the two severity-only RXCs due to their low impact in predicting meaningful differences in risk. Commenters also supported HHS's intention to evaluate the impact of incorporating the prescription drug factors in the model and adding or removing drugs in future model recalibrations as appropriate. Commenters generally supported the inclusion of prescription drug factors in the HHS risk adjustment model, noting the benefit in imputing missing diagnoses. Additionally, we note that commenters on the Request for Information also supported the inclusion of prescription drugs in the risk adjustment methodology. One commenter to the proposed rule suggested HHS should use the MedID for drug classification instead of the RXNorm Concept Unique Identifier (RXCUI) system. The commenter noted MedID would improve stability, accessibility and predictability of the RXCs, as acquiring RXCUI mapping, keeping it up to-date, anticipating changes and ensuring drug inclusion has been a challenge for issuers in determining formularies and often excludes some drugs. Another commenter sought clarification as to whether drugs administered through hospital, office-based or home health settings and found on medical claims would receive credit for the RXC factors, in addition to drugs found on pharmacy claims. One commenter requested HHS release a mapping of RXCUIs to RXC factors for issuers to adequately assess how inclusion and exclusion of drugs will impact risk adjustment, and suggested HHS provide a crosswalk with the RXCUIs mapped to the RXCs prior to January 1, 2018. The commenter also noted that since there is a lag in the data used for recalibration, HHS should consider how to incorporate newer drugs that are approved after the data years and before or during the benefit year. On the other hand, commenters who had a chance to review the draft RXC crosswalk HHS released in September 2017 for the 2018 benefit year risk adjustment adult models suggested that if a drug is included, then all strengths and formulations of that drug ought to be included in the drug class, including the generic or brand name drugs, or requested clarification as to why specific drugs were excluded. A few commenters requested that HHS consider including prescription drugs used by individuals with mental health and substance use disorders in the model, with one suggesting that adding drugs used by those with mental health and substance use disorders to the model may better capture the costs associated with these individuals, and citing a study suggesting that those costs may not be well captured in the associated HCCs in the current model.[14]

Response: We are finalizing our proposal to remove the two severity-only RXCs (RXC 11: Ammonia Detoxicants, and RXC 12: Diuretics, Loop and Select Potassium-Sparing) from the 2019 benefit year risk adjustment adult models. As we explained in the 2018 Payment Notice, we selected the RxNorm tool developed by the U.S. National Library of Medicine because it is frequently updated, reliable, and easily accessible, and issuers commented on the ease of the RxNorm tool in mapping drugs to RXCUIs. As such, we do not see a need to adopt another classification system at this time. HHS posted an RXC to RXCUI draft crosswalk on September 18, 2017,[15] to provide issuers an initial set of RXCUIs that would be included for 2018 benefit year risk adjustment adult models in the HHS-operated risk adjustment program. As we noted in the crosswalk, drugs were excluded based on expert or clinician input as to drugs' cross indications, empirical and statistical analyses that indicated a weak association between the drug and the diagnoses, or if drugs were older or discontinued. Drugs were also excluded in situations where drugs had substantially lower costs compared to other drugs included in the RXC, and therefore these drugs were less likely to be the focus of risk-selection behavior by health plans. In these instances, USP classes contained a mix of newer, more expensive drug treatments, and older, often generic, lower-cost drug treatments. For example, the combined USP classes Immune Suppressants and Immunomodulators encompass a wide range of drugs. They include expensive biologics costing several thousands of dollars each month and drugs like generic methotrexate, a month's supply of which can cost less than $100. Clinician review determined that many of the drugs in this class are substitutable and the general prescribing process would be to first prescribe a cheaper drug, and if the patient does not respond to that then move to a more expensive biologic. However, because concern over patient access and health plan selection behavior (reflected in formulary design) centers around the expensive biologics, the cheaper non-biologics were removed from RXC 9.

We review drugs in the United States Pharmacopeia (USP) classification and consult clinicians and experts to ensure relevant drugs are included. However, as some commenters noted in response to the proposed rule, new drugs have been released since we released the draft 2018 benefit year crosswalk and a few drugs that may be eligible under our other criteria were not classified by the USP classification version used for the draft crosswalk. We expect to publish the final 2018 benefit year crosswalk in the spring of 2019, after the conclusion of the 2018 benefit year, so that newly approved drugs released through the end of the year and the latest USP classification are evaluated and included, as appropriate. As such, we intend to make quarterly updates to the 2018 benefit year prescription drug crosswalk, to ensure we are capturing all new drug releases and drug class inclusions or modifications. We are also reviewing drugs administered through clinicians in hospital, office-based, or

[14] Montz, E., Layton, T., Busch, A.B., Ellis, R.P., Rose, S., & McGuire, T.G. (2016). Risk-adjustment simulation: Plans may have incentives to distort mental health and substance use coverage. Health Affairs, 35(6), 1022–1028.

[15] Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk Memorandum. September 18, 2017. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf.*

2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk. September 18, 2017. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RARx_RxCUIs-Crosswalk-9-6-17.xlsx.*

home health settings crosswalked to national drug codes (NDCs) to determine whether it is appropriate under our inclusion criteria to include these drugs in the 2018 benefit year crosswalk for 2018 benefit year risk adjustment risk score calculation. However, as these drugs are often more expensive when administered in hospital, office-based, or home health settings, we are not including such drugs in the recalibration of the adult models for the 2019 benefit year to limit gaming incentives. We anticipate the 2019 benefit year drug crosswalk will be published on a similar quarterly schedule, following the final 2018 benefit year crosswalk publication. We also intend to monitor the impact of the drugs included in the adult models on prescribing incentives and will evaluate adding or removing other RXCs as appropriate in future recalibrations for future benefit years. We had previously considered, but did not include, antimanic agents for depression and bipolar disorders due to their low imputation value in identifying the risk solely based on the RXC and low relative cost of the drugs. We are continuing to assess if mental health and substance use disorder treatments should be included in the adult models in future benefit years.

Comment: One commenter noted that pharmacy claims should not be included in the risk adjustment data validation process as no clinical documentation is available for pharmacy claims, and HHS should not include data that cannot be easily audited in risk adjustment. Another commenter sought clarification as to how HHS intends to conduct risk adjustment data validation for prescription drugs included in the risk adjustment adult models.

Response: As we noted in the 2018 Payment Notice, HHS does not perform risk adjustment data validation audits with the intent of determining whether a clinician correctly diagnosed a patient. Rather, the goal for the HHS-operated risk adjustment program is to ensure that enrollees' diagnoses on paid claims reflect the appropriately assigned HCCs, and were diagnosed by a licensed clinician. Likewise, in validating pharmacy claims, we intend to validate factors such as whether the prescription was filled and paid by the issuer, and whether the appropriate RXC interaction was assigned. We understand commenters' concerns regarding prescription drug data and intend to closely monitor prescribing behavior in the 2018 benefit year and beyond. We will consider whether additional adjustments to the risk adjustment data validation process are needed for the 2018 benefit year to ensure risk adjustment data validation appropriately audits pharmacy claims submitted to EDGE by issuers.

TABLE 1—FINAL DRUG-DIAGNOSIS (RXC–HCC) PAIRS FOR THE 2019 ADULT MODEL

RXC	RXC label	HCC	HCC label	Final RXC use
RXC 01	Anti-HIV Agents	001	HIV/AIDS	imputation/severity.
RXC 02	Anti-Hepatitis C (HCV) Agents.	037C, 036, 035, 034	Chronic Hepatitis C, Cirrhosis of Liver, End-Stage Liver Disease, and Liver Transplant Status/Complications.	imputation/severity.
RXC 03	Antiarrhythmics	142	Specified Heart Arrhythmias	imputation/severity.
RXC 04	Phosphate Binders	184, 183, 187, 188	End Stage Renal Disease, Kidney Transplant Status, Chronic Kidney Disease, Stage 5, Chronic Kidney Disease, Severe (Stage 4).	imputation/severity.
RXC 05	Inflammatory Bowel Disease Agents.	048, 041	Inflammatory Bowel Disease, Intestine Transplant Status/Complications.	imputation/severity.
RXC 06	Insulin	019, 020, 021, 018	Diabetes with Acute Complications; Diabetes with Chronic Complications; Diabetes without Complication, Pancreas Transplant Status/Complications.	imputation/severity.
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only.	019, 020, 021, 018	Diabetes with Acute Complications, Diabetes with Chronic Complications, Diabetes without Complication, Pancreas Transplant Status/Complications.	imputation/severity.
RXC 08	Multiple Sclerosis Agents	118	Multiple Sclerosis	imputation/severity.
RXC 09	Immune Suppressants and Immunomodulators.	056, 057, 048, 041	Rheumatoid Arthritis and Specified Autoimmune Disorders, Systemic Lupus Erythematosus and Other Autoimmune Disorders, Inflammatory Bowel Disease, Intestine Transplant Status/Complications.	imputation/severity.
RXC 10	Cystic Fibrosis Agents	159, 158	Cystic Fibrosis, Lung Transplant Status/Complications.	imputation/severity.

iii. High-Cost Risk Pool Adjustment

HHS finalized a high-cost risk pool adjustment in the 2018 Payment Notice to account for the incorporation of risk associated with high-cost enrollees in the risk adjustment model. Specifically, we finalized adjusting the risk adjustment model for high-cost enrollees beginning for the 2018 benefit year by excluding a percentage of costs above a certain threshold level in the calculation of enrollee-level plan liability risk scores so that risk adjustment factors are calculated without the high-cost risk, because the average risk associated with HCCs and RXCs is better accounted for without the inclusion of the high-cost enrollees. In addition, to account for issuers' risk associated with the high-cost enrollees, issuers will be compensated for a percentage of costs above the threshold. We set the threshold and percentage of costs at a level that would continue to incentivize issuers to control costs while improving the risk prediction of the risk adjustment model. Issuers with high-cost enrollees will receive a payment for the percentage of costs above the threshold in their respective transfers. Using claims data submitted to the EDGE server by issuers of risk adjustment covered plans, HHS will calculate the total amount of paid claims costs for high-cost enrollees based on the threshold and the coinsurance rate. HHS will then calculate a charge as a percentage of the issuers' total premiums in the individual (including catastrophic and non-catastrophic plans and merged

market plans), or small group markets, which will be applied to the total transfer amount in that market, maintaining the balance of payments and charges within the risk adjustment program. In the 2018 Payment Notice, we finalized a threshold of $1 million and a coinsurance rate of 60 percent across all States for the individual (including catastrophic and non-catastrophic plans and merged market plans) and small group markets for the 2018 benefit year.

For the 2019 benefit year, we proposed to maintain the same parameters that apply to the 2018 benefit year. Therefore, we proposed to maintain a $1 million threshold and 60 percent coinsurance rate for the high-cost risk pool for the 2019 benefit year risk adjustment program. We explained that we believe this threshold and coinsurance rate would result in total payments or charges nationally that are very small as a percentage of premiums for issuers, and will prevent States and issuers with very high-cost enrollees from bearing a disproportionate amount of unpredictable risk. We sought comments on alternative methods for reimbursing issuers for exceptionally high-cost enrollees through the high-cost risk pool and improving the calculation of plan liability in the HHS-operated risk adjustment models for future benefit years. We also shared suggestions from stakeholders that the pool be multi-tiered, with multiple thresholds and increased coinsurance as the thresholds increase to account for the reduced number of enrollees at higher thresholds where costs to an issuer are catastrophic.

We are finalizing the high-cost risk pool adjustment parameters for the 2019 benefit year as proposed.

Comment: Most commenters supported our proposal to maintain the same high-cost risk pool adjustment parameters as those used for the 2018 benefit year and noted that keeping the parameters the same provides stability and certainty in the markets. One commenter questioned why the parameters are not trended for increasing medical costs. Some commenters noted that the $1 million threshold level may be too high to have any meaningful impact on premiums or provide stability in smaller State markets with low claims costs that would have additional charges assessed, which could cause volatility. A few commenters did not support the high-cost risk pool adjustment to transfers, yet one of these commenters supported the removal of these costs from the risk adjustment model recalibration. One commenter did not support the proposal based on what appears to be a misunderstanding that the high-cost risk pool adjustment requires individuals to pay 40 percent of costs above $1 million. Some commenters did not support tiering the high-cost risk pool adjustment program for the 2019 benefit year without the first year of experience with this adjustment, noting it would lead to additional complexity. One commenter supported a tiered approach in parameters with maximum coinsurance rates of 80 to 90 percent phased in over multiple years, and another commenter supported a tiered approach if the approach and parameters result in an equivalent cost and scope as the $1 million threshold and 60 percent coinsurance rate parameters.

Response: As we noted in the 2018 Payment Notice, removing extremely high costs improves the risk adjustment model's predictive ability. Additionally, the high-cost risk pool adjustment to the transfer formula mitigates issuers' risk selection incentives to avoid high-cost risk enrollees. Because high-cost enrollees are outliers and thus, unpredictable, they have the potential to significantly distort risk in smaller markets. Removing the high-cost risk from the recalibration model and separately adjusting transfers will allow for greater stability in risk scores to compensate issuers for predictable risk and transfers to compensate issuers for unpredictable risk. We will consider whether a tiered approach would improve model prediction and better compensate issuers for high-cost enrollees than the current approach for future benefit years. We are continuing to assess the market impact of tiered approaches nationally on the model's risk prediction and issuers' risk differences, and whether such an approach would meaningfully improve the model in accounting for high-cost enrollees' risk. We continue to believe a $1 million threshold and 60 percent coinsurance rate for the 2019 benefit year are appropriate to incentivize issuers to control costs while improving the risk adjustment model's risk prediction. Additionally, as we noted in the 2018 Payment Notice, if an issuer were to fail the data quality analysis for a risk adjustment transfer and be assessed a default charge under § 153.740(b) on that basis, we would perform additional data quality analysis to determine an issuer's eligibility for high-cost risk pool adjustments.

We are finalizing our proposal to maintain a $1 million threshold and 60 percent coinsurance rate for the high-cost risk pool for the 2019 benefit year risk adjustment program.

c. List of Factors To Be Employed in the Risk Adjustment Model (§ 153.320)

The final factors resulting from the equally weighted blended factors from the 2014 and 2015 MarketScan® data and the 2016 enrollee-level EDGE data separately solved models (with the incorporation of the partial year enrollment adjustment and prescription drugs reflected in the adult models only) are shown in Tables 2, 4, and 5. The adult, child and infant models have been truncated to account for the high-cost enrollee pool payment parameters by removing 60 percent of costs above the $1 million threshold as finalized in this rule. As discussed in the preceding section, we are finalizing our proposal to keep the 2019 benefit year high-cost enrollee risk pool payment parameters the same as those finalized for the 2018 benefit year. The final factors for the adult models also reflect the removal of the two severity-only RXCs (RXC 11: Ammonia Detoxicants, and RXC 12: Diuretics, Loop and Select Potassium-Sparing) discussed above in the preamble section on ''Prescription Drugs.'' Table 2 contains factors for each adult model, including the age-sex, HCCs, RXCs, HCC–RXC interaction, and enrollment duration coefficients. As we previously noted,[16] some interactions of RXCs and HCCs have negative coefficients; however, this does not mean that an enrollee's risk score decreases due to the presence of an RXC, an HCC, or both.

Table 3 contains the HHS HCCs in the severity illness indicator variable. Table 4 contains the factors for each child model. Table 5 contains the factors for each infant model. Tables 6 and 7 contain the HCCs included in the infant model maturity and severity categories, respectively.

Comment: A few commenters requested for HHS to separately publish the coefficients solved only from the 2016 enrollee-level EDGE data.

Response: We are not separately publishing the coefficients from only 1 year of data to avoid any confusion that could be caused from publishing two sets of coefficients in the final rule. However, we note that stakeholders interested in coefficients from the 2016 enrollee-level EDGE data will be able to solve for them based on the proposed and finalized coefficients. We published the model coefficients using equally weighted coefficients solved from the

[16] 2018 Benefit Year Final HHS Risk Adjustment Model Coefficients. April 18, 2017. Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/2018-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.*

2014 and 2015 MarketScan® data in the proposed rule. The coefficients finalized in Tables 2, 4 and 5 include the coefficients solved from the 2016 enrollee-level EDGE data without changing the coefficients solved from the 2014 and 2015 MarketScan® data published in the proposed rule, and equally weighted coefficients solved from the 3 years of data.

TABLE 2—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
	Demographic Factors					
	Age 21–24, Male	0.167	0.133	0.091	0.051	0.048
	Age 25–29, Male	0.153	0.119	0.078	0.037	0.034
	Age 30–34, Male	0.186	0.144	0.093	0.043	0.039
	Age 35–39, Male	0.236	0.185	0.125	0.063	0.058
	Age 40–44, Male	0.292	0.233	0.164	0.093	0.088
	Age 45–49, Male	0.346	0.280	0.202	0.121	0.115
	Age 50–54, Male	0.455	0.378	0.287	0.192	0.184
	Age 55–59, Male	0.511	0.424	0.324	0.217	0.209
	Age 60–64, Male	0.573	0.473	0.359	0.235	0.225
	Age 21–24, Female	0.269	0.218	0.153	0.088	0.083
	Age 25–29, Female	0.304	0.245	0.173	0.098	0.092
	Age 30–34, Female	0.410	0.338	0.253	0.167	0.160
	Age 35–39, Female	0.491	0.410	0.317	0.226	0.219
	Age 40–44, Female	0.545	0.454	0.352	0.249	0.241
	Age 45–49, Female	0.553	0.458	0.350	0.237	0.229
	Age 50–54, Female	0.616	0.516	0.401	0.278	0.268
	Age 55–59, Female	0.601	0.499	0.380	0.252	0.241
	Age 60–64, Female	0.616	0.505	0.379	0.240	0.229
	Diagnosis Factors					
HCC001	HIV/AIDS	0.626	0.529	0.434	0.359	0.352
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	8.000	7.812	7.688	7.731	7.737
HCC003	Central Nervous System Infections, Except Viral Meningitis	5.750	5.666	5.604	5.625	5.626
HCC004	Viral or Unspecified Meningitis	4.396	4.192	4.060	3.989	3.983
HCC006	Opportunistic Infections	6.143	6.060	6.006	5.972	5.968
HCC008	Metastatic Cancer	21.806	21.372	21.040	21.084	21.087
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	12.392	12.068	11.825	11.807	11.804
HCC010	Non-Hodgkin's Lymphomas and Other Cancers and Tumors	5.575	5.356	5.189	5.117	5.110
HCC011	Colorectal, Breast (Age <50), Kidney, and Other Cancers	4.291	4.074	3.905	3.831	3.823
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.	2.640	2.482	2.356	2.283	2.276
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.	1.211	1.084	0.976	0.860	0.849
HCC018	Pancreas Transplant Status/Complications	4.439	4.246	4.114	4.122	4.122
HCC019	Diabetes with Acute Complications	0.603	0.531	0.463	0.389	0.381
HCC020	Diabetes with Chronic Complications	0.603	0.531	0.463	0.389	0.381
HCC021	Diabetes without Complication	0.603	0.531	0.463	0.389	0.381
HCC023	Protein-Calorie Malnutrition	11.438	11.430	11.416	11.494	11.502
HCC026	Mucopolysaccharidosis	2.380	2.280	2.200	2.137	2.132
HCC027	Lipidoses and Glycogenosis	2.380	2.280	2.200	2.137	2.132
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders	NA	NA	NA	NA	NA
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders	2.380	2.280	2.200	2.137	2.132
HCC034	Liver Transplant Status/Complications	2.380	2.280	2.200	2.137	2.132
HCC035	End-Stage Liver Disease	10.515	10.418	10.353	10.334	10.331
HCC036	Cirrhosis of Liver	5.696	5.491	5.349	5.341	5.339
HCC037_1	Chronic Viral Hepatitis C	0.707	0.604	0.545	0.509	0.505
HCC037_2	Chronic Hepatitis, Other/Unspecified	0.703	0.584	0.523	0.474	0.469
HCC038	Acute Liver Failure/Disease, Including Neonatal Hepatitis	4.300	4.155	4.055	4.026	4.024
HCC041	Intestine Transplant Status/Complications	28.253	28.206	28.169	28.209	28.209
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	9.718	9.488	9.318	9.328	9.329
HCC045	Intestinal Obstruction	5.510	5.274	5.115	5.104	5.102
HCC046	Chronic Pancreatitis	4.439	4.246	4.114	4.122	4.122
HCC047	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.	2.243	2.085	1.972	1.896	1.888
HCC048	Inflammatory Bowel Disease	2.192	2.011	1.868	1.765	1.755
HCC054	Necrotizing Fasciitis	5.507	5.332	5.200	5.206	5.207
HCC055	Bone/Joint/Muscle Infections/Necrosis	5.507	5.332	5.200	5.206	5.207
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders	3.316	3.130	2.980	2.923	2.918
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.993	0.878	0.780	0.666	0.654
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies	2.654	2.477	2.337	2.257	2.249
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders	2.654	2.477	2.337	2.257	2.249
HCC063	Cleft Lip/Cleft Palate	1.417	1.266	1.155	1.071	1.065
HCC066	Hemophilia	53.096	52.795	52.549	52.553	52.553
HCC067	Myelodysplastic Syndromes and Myelofibrosis	12.454	12.326	12.228	12.227	12.227
HCC068	Aplastic Anemia	12.454	12.326	12.228	12.227	12.227
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	7.864	7.738	7.636	7.604	7.602
HCC070	Sickle Cell Anemia (Hb–SS)	7.864	7.738	7.636	7.604	7.602
HCC071	Thalassemia Major	7.864	7.738	7.636	7.604	7.602
HCC073	Combined and Other Severe Immunodeficiencies	5.198	5.074	4.982	4.979	4.979
HCC074	Disorders of the Immune Mechanism	5.198	5.074	4.982	4.979	4.979
HCC075	Coagulation Defects and Other Specified Hematological Disorders	2.657	2.572	2.503	2.464	2.461
HCC081	Drug Psychosis	3.804	3.574	3.401	3.278	3.265

TABLE 2—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC082	Drug Dependence	3.804	3.574	3.401	3.278	3.265
HCC087	Schizophrenia	3.057	2.822	2.651	2.559	2.550
HCC088	Major Depressive and Bipolar Disorders	1.624	1.472	1.350	1.231	1.219
HCC089	Reactive and Unspecified Psychosis, Delusional Disorders	1.624	1.472	1.350	1.231	1.219
HCC090	Personality Disorders	1.124	1.010	0.901	0.780	0.769
HCC094	Anorexia/Bulimia Nervosa	2.549	2.397	2.275	2.201	2.194
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	4.019	3.924	3.847	3.789	3.783
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.	1.056	0.963	0.880	0.802	0.795
HCC102	Autistic Disorder	1.124	1.010	0.901	0.780	0.769
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder	1.124	1.010	0.901	0.780	0.769
HCC106	Traumatic Complete Lesion Cervical Spinal Cord	9.989	9.853	9.752	9.735	9.732
HCC107	Quadriplegia	9.989	9.853	9.752	9.735	9.732
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord	7.568	7.420	7.310	7.278	7.274
HCC109	Paraplegia	7.568	7.420	7.310	7.278	7.274
HCC110	Spinal Cord Disorders/Injuries	5.212	5.008	4.857	4.816	4.812
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	1.965	1.764	1.620	1.534	1.524
HCC112	Quadriplegic Cerebral Palsy	0.302	0.192	0.120	0.072	0.071
HCC113	Cerebral Palsy, Except Quadriplegic	0.255	0.176	0.120	0.072	0.071
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.	0.355	0.300	0.265	0.241	0.236
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	5.262	5.137	5.045	5.027	5.025
HCC117	Muscular Dystrophy	2.064	1.922	1.819	1.720	1.708
HCC118	Multiple Sclerosis	8.436	8.144	7.920	7.895	7.892
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.	2.064	1.922	1.819	1.720	1.708
HCC120	Seizure Disorders and Convulsions	1.390	1.248	1.138	1.044	1.035
HCC121	Hydrocephalus	5.922	5.814	5.724	5.696	5.694
HCC122	Non-Traumatic Coma, and Brain Compression/Anoxic Damage	8.310	8.176	8.067	8.059	8.058
HCC125	Respirator Dependence/Tracheostomy Status	26.626	26.590	26.555	26.637	26.644
HCC126	Respiratory Arrest	8.048	7.900	7.794	7.864	7.872
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.	8.048	7.900	7.794	7.864	7.872
HCC128	Heart Assistive Device/Artificial Heart	28.421	28.219	28.071	28.120	28.125
HCC129	Heart Transplant	28.421	28.219	28.071	28.120	28.125
HCC130	Congestive Heart Failure	2.800	2.705	2.635	2.624	2.623
HCC131	Acute Myocardial Infarction	8.077	7.789	7.577	7.664	7.672
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease	4.820	4.558	4.388	4.378	4.378
HCC135	Heart Infection/Inflammation, Except Rheumatic	5.473	5.356	5.268	5.237	5.235
HCC142	Specified Heart Arrhythmias	2.467	2.335	2.233	2.158	2.150
HCC145	Intracranial Hemorrhage	7.621	7.366	7.186	7.162	7.159
HCC146	Ischemic or Unspecified Stroke	2.164	2.012	1.918	1.896	1.894
HCC149	Cerebral Aneurysm and Arteriovenous Malformation	3.167	2.994	2.869	2.802	2.796
HCC150	Hemiplegia/Hemiparesis	4.517	4.422	4.355	4.402	4.407
HCC151	Monoplegia, Other Paralytic Syndromes	2.734	2.612	2.525	2.486	2.482
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene	9.056	8.976	8.915	9.004	9.013
HCC154	Vascular Disease with Complications	6.714	6.556	6.439	6.424	6.422
HCC156	Pulmonary Embolism and Deep Vein Thrombosis	3.352	3.207	3.101	3.044	3.038
HCC158	Lung Transplant Status/Complications	25.564	25.421	25.310	25.384	25.391
HCC159	Cystic Fibrosis	14.108	13.825	13.596	13.601	13.601
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.878	0.776	0.686	0.591	0.582
HCC161	Asthma	0.878	0.776	0.686	0.591	0.582
HCC162	Fibrosis of Lung and Other Lung Disorders	1.869	1.767	1.693	1.639	1.633
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	6.270	6.223	6.188	6.194	6.195
HCC183	Kidney Transplant Status	7.462	7.260	7.119	7.070	7.064
HCC184	End Stage Renal Disease	29.905	29.678	29.495	29.641	29.654
HCC187	Chronic Kidney Disease, Stage 5	1.319	1.263	1.224	1.233	1.235
HCC188	Chronic Kidney Disease, Stage 4	1.319	1.263	1.224	1.233	1.235
HCC203	Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism.	1.156	1.011	0.879	0.670	0.648
HCC204	Miscarriage with Complications	1.156	1.011	0.879	0.670	0.648
HCC205	Miscarriage with No or Minor Complications	1.156	1.011	0.879	0.670	0.648
HCC207	Completed Pregnancy With Major Complications	3.329	2.913	2.690	2.416	2.386
HCC208	Completed Pregnancy With Complications	3.329	2.913	2.690	2.416	2.386
HCC209	Completed Pregnancy with No or Minor Complications	3.329	2.913	2.690	2.416	2.386
HCC217	Chronic Ulcer of Skin, Except Pressure	1.988	1.888	1.818	1.798	1.796
HCC226	Hip Fractures and Pathological Vertebral or Humerus Fractures	8.801	8.587	8.428	8.457	8.460
HCC227	Pathological Fractures, Except of Vertebrae, Hip, or Humerus	3.874	3.744	3.644	3.579	3.575
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications	24.334	24.334	24.329	24.357	24.360
HCC253	Artificial Openings for Feeding or Elimination	8.284	8.198	8.131	8.164	8.168
HCC254	Amputation Status, Lower Limb/Amputation Complications	3.486	3.371	3.290	3.313	3.316
	Interaction Factors					
SEVERE x HCC006	Severe illness x Opportunistic Infections	7.694	7.897	8.035	8.180	8.193
SEVERE x HCC008	Severe illness x Metastatic Cancer	7.694	7.897	8.035	8.180	8.193
SEVERE x HCC009	Severe illness x Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	7.694	7.897	8.035	8.180	8.193
SEVERE x HCC010	Severe illness x Non-Hodgkin's Lymphomas and Other Cancers and Tumors.	7.694	7.897	8.035	8.180	8.193

TABLE 2—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
SEVERE x HCC115	Severe illness x Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	7.694	7.897	8.035	8.180	8.193
SEVERE x HCC135	Severe illness x Heart Infection/Inflammation, Except Rheumatic	7.694	7.897	8.035	8.180	8.193
SEVERE x HCC145	Severe illness x Intracranial Hemorrhage	7.694	7.897	8.035	8.180	8.193
SEVERE x G06	Severe illness x HCC group G06 (G06 is HCC Group 6 which includes the following HCCs in the blood disease category: 67, 68).	7.694	7.897	8.035	8.180	8.193
SEVERE x G08	Severe illness x HCC group G08 (G08 is HCC Group 8 which includes the following HCCs in the blood disease category: 73, 74).	7.694	7.897	8.035	8.180	8.193
SEVERE x HCC035	Severe illness x End-Stage Liver Disease	1.449	1.541	1.596	1.722	1.733
SEVERE x HCC038	Severe illness x Acute Liver Failure/Disease, Including Neonatal Hepatitis	1.449	1.541	1.596	1.722	1.733
SEVERE x HCC153	Severe illness x Atherosclerosis of the Extremities with Ulceration or Gangrene.	1.449	1.541	1.596	1.722	1.733
SEVERE x HCC154	Severe illness x Vascular Disease with Complications	1.449	1.541	1.596	1.722	1.733
SEVERE x HCC163	Severe illness x Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	1.449	1.541	1.596	1.722	1.733
SEVERE x HCC253	Severe illness x Artificial Openings for Feeding or Elimination	1.449	1.541	1.596	1.722	1.733
SEVERE x G03	Severe illness x HCC group G03 (G03 is HCC Group 3 which includes the following HCCs in the musculoskeletal disease category: 54, 55).	1.449	1.541	1.596	1.722	1.733
	Enrollment Duration Factors					
	1 month of enrollment	0.417	0.365	0.325	0.306	0.305
	2 months of enrollment	0.382	0.333	0.293	0.275	0.273
	3 months of enrollment	0.327	0.282	0.244	0.227	0.225
	4 months of enrollment	0.279	0.240	0.206	0.189	0.188
	5 months of enrollment	0.249	0.216	0.185	0.169	0.168
	6 months of enrollment	0.207	0.181	0.153	0.138	0.137
	7 months of enrollment	0.189	0.165	0.141	0.126	0.125
	8 months of enrollment	0.137	0.120	0.102	0.091	0.091
	9 months of enrollment	0.097	0.085	0.074	0.067	0.067
	10 months of enrollment	0.070	0.065	0.060	0.057	0.057
	11 months of enrollment	0.064	0.060	0.057	0.055	0.055
	Prescription Drug Factors					
RXC 01	Anti-HIV Agents	7.822	7.257	6.830	6.605	6.580
RXC 02	Anti-Hepatitis C (HCV) Agents	39.880	39.337	38.905	39.062	39.075
RXC 03	Antiarrhythmics	0.113	0.113	0.113	0.113	0.113
RXC 04	Phosphate Binders	0.730	0.730	0.730	0.730	0.730
RXC 05	Inflammatory Bowel Disease Agents	2.022	1.842	1.701	1.509	1.487
RXC 06	Insulin	1.498	1.349	1.185	0.993	0.973
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only	0.495	0.430	0.361	0.272	0.264
RXC 08	Multiple Sclerosis Agents	21.141	20.350	19.757	19.731	19.721
RXC 09	Immune Suppressants and Immunomodulators	13.273	12.681	12.240	12.270	12.268
RXC 10	Cystic Fibrosis Agents	13.045	12.712	12.485	12.565	12.574
RXC 01 x HCC001	Additional effect for enrollees with RXC 01 (Anti-HIV Agents) and HCC 001 (HIV/AIDS).	2.459	2.560	2.655	3.010	3.046
RXC 02 x HCC037_1, 036, 035, 034.	Additional effect for enrollees with RXC 02 (Anti-Hepatitis C (HCV) Agents) and (HCC 037_1 (Chronic Viral Hepatitis C) or 036 (Cirrhosis of Liver) or 035 (End-Stage Liver Disease) or 034 (Liver Transplant Status/Complications)).	2.645	2.838	2.974	3.020	3.025
RXC 03 x HCC142	Additional effect for enrollees with RxC 03 (Antiarrhythmics) and HCC 142 (Specified Heart Arrhythmias).	0.000	0.000	0.000	0.000	0.000
RXC 04 x HCC184, 183, 187, 188.	Additional effect for enrollees with RxC 04 (Phosphate Binders) and (HCC 184 (End Stage Renal Disease) or 183 (Kidney Transplant Status) or 187 (Chronic Kidney Disease, Stage 5) or 188 (Chronic Kidney Disease, Severe Stage 4)).	0.000	0.000	0.000	0.000	0.000
RXC 05 x HCC048, 041	Additional effect for enrollees with RxC 05 (Inflammatory Bowel Disease Agents) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)).	−1.192	−1.096	−0.997	−0.888	−0.878
RXC 06 x HCC018, 019, 020, 021.	Additional effect for enrollees with RxC 06 (Insulin) and (HCC 018 (Pancreas Transplant Status/Complications) or 019 (Diabetes with Acute Complications) or 020 (Diabetes with Chronic Complications) or 021 (Diabetes without Complication)).	0.421	0.395	0.456	0.533	0.538
RXC 07 x HCC018, 019, 020, 021.	Additional effect for enrollees with RxC 07 (Anti-Diabetic Agents, Except Insulin and Metformin Only) and (HCC 018 (Pancreas Transplant Status/Complications) or 019 (Diabetes with Acute Complications) or 020 (Diabetes with Chronic Complications) or 021 (Diabetes without Complication)).	−0.202	−0.184	−0.153	−0.153	−0.155
RXC 08 x HCC118	Additional effect for enrollees with RxC 08 (Multiple Sclerosis Agents) and HCC 118 (Multiple Sclerosis).	−5.507	−4.981	−4.597	−4.422	−4.399
RXC 09 x HCC056 or 057 and 048 or 041.	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)) and (HCC 056 (Rheumatoid Arthritis and Specified Autoimmune Disorders) or 057 (Systemic Lupus Erythematosus and Other Autoimmune Disorders)).	−0.337	−0.352	−0.336	−0.370	−0.375
RXC 09 x HCC056	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and HCC 056 (Rheumatoid Arthritis and Specified Autoimmune Disorders).	−2.862	−2.632	−2.452	−2.323	−2.307
RXC 09 x HCC057	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and HCC 057 (Systemic Lupus Erythematosus and Other Autoimmune Disorders).	−0.595	−0.444	−0.322	−0.175	−0.161

TABLE 2—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC 09 x HCC048, 041	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)).	1.128	1.392	1.563	1.764	1.788
RXC 10 x HCC159, 158	Additional effect for enrollees with RxC 10 (Cystic Fibrosis Agents) and (HCC 159 (Cystic Fibrosis) or 158 (Lung Transplant Status/Complications)).	29.170	29.398	29.528	29.588	29.594

TABLE 3—HHS HCCS IN THE SEVERITY ILLNESS INDICATOR VARIABLE

Description
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Peritonitis/Gastrointestinal Perforation/Necrotizing Enter colitis.
Seizure Disorders and Convulsions.
Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Respirator Dependence/Tracheostomy Status.
Respiratory Arrest.
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Pulmonary Embolism and Deep Vein Thrombosis.

TABLE 4—FINAL CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.200	0.149	0.092	0.042	0.038
Age 5–9, Male	0.138	0.100	0.055	0.018	0.015
Age 10–14, Male	0.193	0.152	0.100	0.060	0.058
Age 15–20, Male	0.258	0.209	0.151	0.099	0.095
Age 2–4, Female	0.153	0.109	0.062	0.025	0.022
Age 5–9, Female	0.102	0.068	0.031	0.005	0.003
Age 10–14, Female	0.182	0.142	0.095	0.059	0.056
Age 15–20, Female	0.281	0.224	0.155	0.091	0.086
Diagnosis Factors					
HIV/AIDS	5.368	4.942	4.622	4.506	4.493
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	13.803	13.633	13.522	13.529	13.530
Central Nervous System Infections, Except Viral Meningitis	8.179	8.020	7.905	7.913	7.913
Viral or Unspecified Meningitis	3.563	3.358	3.225	3.077	3.063
Opportunistic Infections	16.934	16.887	16.848	16.832	16.829
Metastatic Cancer	32.479	32.270	32.092	32.101	32.102
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	10.021	9.785	9.590	9.509	9.501
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	7.835	7.601	7.411	7.304	7.292
Colorectal, Breast (Age <50), Kidney, and Other Cancers	3.051	2.879	2.737	2.618	2.605
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.051	2.879	2.737	2.618	2.605
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.188	1.057	0.943	0.818	0.805
Pancreas Transplant Status/Complications	22.337	22.078	21.875	21.901	21.904
Diabetes with Acute Complications	2.550	2.234	2.032	1.749	1.721
Diabetes with Chronic Complications	2.550	2.234	2.032	1.749	1.721
Diabetes without Complication	2.550	2.234	2.032	1.749	1.721
Protein-Calorie Malnutrition	12.783	12.694	12.618	12.658	12.661
Mucopolysaccharidosis	7.948	7.723	7.536	7.494	7.489
Lipidoses and Glycogenosis	7.948	7.723	7.536	7.494	7.489
Congenital Metabolic Disorders, Not Elsewhere Classified	7.948	7.723	7.536	7.494	7.489
Amyloidosis, Porphyria, and Other Metabolic Disorders	7.948	7.723	7.536	7.494	7.489
Adrenal, Pituitary, and Other Significant Endocrine Disorders	7.948	7.723	7.536	7.494	7.489
Liver Transplant Status/Complications	22.337	22.078	21.875	21.901	21.904
End-Stage Liver Disease	11.834	11.685	11.584	11.580	11.579
Cirrhosis of Liver	5.782	5.646	5.535	5.507	5.507
Chronic Viral Hepatitis C	6.269	6.114	5.983	5.966	5.967
Chronic Hepatitis, Other/Unspecified	1.200	1.086	0.983	0.923	0.920
Acute Liver Failure/Disease, Including Neonatal Hepatitis	11.636	11.494	11.390	11.392	11.391

TABLE 4—FINAL CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Intestine Transplant Status/Complications	22.337	22.078	21.875	21.901	21.904
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	11.572	11.283	11.063	11.060	11.061
Intestinal Obstruction	4.506	4.310	4.154	4.057	4.049
Chronic Pancreatitis	10.521	10.314	10.163	10.167	10.167
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	2.265	2.148	2.046	1.948	1.938
Inflammatory Bowel Disease	7.055	6.685	6.402	6.291	6.279
Necrotizing Fasciitis	3.907	3.706	3.544	3.468	3.461
Bone/Joint/Muscle Infections/Necrosis	3.907	3.706	3.544	3.468	3.461
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.282	4.052	3.856	3.762	3.754
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.092	0.970	0.854	0.726	0.714
Osteogenesis Imperfecta and Other Osteodystrophies	1.402	1.292	1.193	1.110	1.102
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.402	1.292	1.193	1.110	1.102
Cleft Lip/Cleft Palate	1.435	1.260	1.121	0.992	0.980
Hemophilia	61.183	60.705	60.325	60.299	60.296
Myelodysplastic Syndromes and Myelofibrosis	14.718	14.596	14.505	14.474	14.470
Aplastic Anemia	14.718	14.596	14.505	14.474	14.470
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	6.928	6.714	6.544	6.456	6.448
Sickle Cell Anemia (Hb–SS)	6.928	6.714	6.544	6.456	6.448
Thalassemia Major	6.928	6.714	6.544	6.456	6.448
Combined and Other Severe Immunodeficiencies	5.849	5.705	5.592	5.531	5.526
Disorders of the Immune Mechanism	5.849	5.705	5.592	5.531	5.526
Coagulation Defects and Other Specified Hematological Disorders	4.662	4.542	4.439	4.366	4.359
Drug Psychosis	5.648	5.392	5.211	5.131	5.125
Drug Dependence	5.648	5.392	5.211	5.131	5.125
Schizophrenia	4.819	4.473	4.217	4.086	4.073
Major Depressive and Bipolar Disorders	2.214	2.007	1.833	1.653	1.636
Reactive and Unspecified Psychosis, Delusional Disorders	2.129	1.931	1.762	1.584	1.567
Personality Disorders	0.622	0.517	0.405	0.257	0.243
Anorexia/Bulimia Nervosa	2.657	2.471	2.318	2.238	2.228
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	2.119	1.961	1.850	1.796	1.790
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.785	1.639	1.526	1.435	1.427
Autistic Disorder	2.017	1.836	1.677	1.511	1.495
Pervasive Developmental Disorders, Except Autistic Disorder	0.686	0.592	0.484	0.349	0.338
Traumatic Complete Lesion Cervical Spinal Cord	11.525	11.463	11.427	11.507	11.514
Quadriplegia	11.525	11.463	11.427	11.507	11.514
Traumatic Complete Lesion Dorsal Spinal Cord	9.265	9.094	8.948	8.933	8.928
Paraplegia	9.265	9.094	8.948	8.933	8.928
Spinal Cord Disorders/Injuries	3.678	3.487	3.339	3.247	3.239
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	4.952	4.754	4.592	4.506	4.499
Quadriplegic Cerebral Palsy	2.968	2.768	2.638	2.642	2.642
Cerebral Palsy, Except Quadriplegic	0.496	0.392	0.322	0.263	0.261
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.422	1.303	1.209	1.137	1.130
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	9.749	9.588	9.461	9.440	9.440
Muscular Dystrophy	2.584	2.410	2.280	2.179	2.168
Multiple Sclerosis	10.447	10.104	9.835	9.801	9.797
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	2.584	2.410	2.280	2.179	2.168
Seizure Disorders and Convulsions	2.004	1.852	1.714	1.567	1.553
Hydrocephalus	4.256	4.146	4.063	4.044	4.042
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	5.714	5.590	5.487	5.444	5.440
Respirator Dependence/Tracheostomy Status	31.959	31.852	31.774	31.912	31.924
Respiratory Arrest	9.776	9.552	9.401	9.366	9.360
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	9.776	9.552	9.401	9.366	9.360
Heart Assistive Device/Artificial Heart	22.337	22.078	21.875	21.901	21.904
Heart Transplant	22.337	22.078	21.875	21.901	21.904
Congestive Heart Failure	5.773	5.674	5.588	5.545	5.540
Acute Myocardial Infarction	5.179	5.104	5.062	5.048	5.046
Unstable Angina and Other Acute Ischemic Heart Disease	3.842	3.765	3.707	3.676	3.675

TABLE 4—FINAL CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Heart Infection/Inflammation, Except Rheumatic	11.892	11.786	11.703	11.684	11.683
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	4.742	4.584	4.427	4.311	4.301
Major Congenital Heart/Circulatory Disorders	1.345	1.248	1.130	1.012	1.002
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.876	0.787	0.684	0.591	0.584
Specified Heart Arrhythmias	3.734	3.576	3.438	3.360	3.353
Intracranial Hemorrhage	12.674	12.462	12.308	12.302	12.303
Ischemic or Unspecified Stroke	5.445	5.367	5.318	5.328	5.331
Cerebral Aneurysm and Arteriovenous Malformation	3.374	3.188	3.056	2.980	2.972
Hemiplegia/Hemiparesis	4.146	4.041	3.967	3.933	3.927
Monoplegia, Other Paralytic Syndromes	3.501	3.373	3.284	3.255	3.254
Atherosclerosis of the Extremities with Ulceration or Gangrene	11.717	11.481	11.305	11.230	11.223
Vascular Disease with Complications	14.161	14.049	13.958	13.980	13.981
Pulmonary Embolism and Deep Vein Thrombosis	13.582	13.475	13.396	13.432	13.436
Lung Transplant Status/Complications	22.337	22.078	21.875	21.901	21.904
Cystic Fibrosis	22.337	22.078	21.875	21.901	21.904
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.375	0.310	0.225	0.134	0.126
Asthma	0.375	0.310	0.225	0.134	0.126
Fibrosis of Lung and Other Lung Disorders	3.073	2.971	2.872	2.801	2.795
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	8.178	8.122	8.074	8.105	8.108
Kidney Transplant Status	12.436	12.166	11.969	11.943	11.938
End Stage Renal Disease	36.073	35.963	35.872	35.976	35.985
Chronic Kidney Disease, Stage 5	4.148	4.017	3.909	3.812	3.806
Chronic Kidney Disease, Severe (Stage 4)	4.148	4.017	3.909	3.812	3.806
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.061	0.906	0.761	0.532	0.507
Miscarriage with Complications	1.061	0.906	0.761	0.532	0.507
Miscarriage with No or Minor Complications	1.061	0.906	0.761	0.532	0.507
Completed Pregnancy With Major Complications	2.897	2.512	2.294	1.986	1.950
Completed Pregnancy With Complications	2.897	2.512	2.294	1.986	1.950
Completed Pregnancy with No or Minor Complications	2.897	2.512	2.294	1.986	1.950
Chronic Ulcer of Skin, Except Pressure	2.338	2.247	2.159	2.086	2.079
Hip Fractures and Pathological Vertebral or Humerus Fractures	5.437	5.163	4.942	4.830	4.822
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	1.665	1.535	1.404	1.262	1.248
Stem Cell, Including Bone Marrow, Transplant Status/Complications	22.337	22.078	21.875	21.901	21.904
Artificial Openings for Feeding or Elimination	11.371	11.258	11.185	11.294	11.305
Amputation Status, Lower Limb/Amputation Complications	6.737	6.497	6.322	6.207	6.195

TABLE 5—FINAL INFANT RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	253.927	252.583	251.467	251.462	251.464
Extremely Immature * Severity Level 4	154.510	153.094	151.930	151.820	151.808
Extremely Immature * Severity Level 3	33.920	32.887	32.017	31.768	31.749
Extremely Immature * Severity Level 2	33.920	32.887	32.017	31.768	31.749
Extremely Immature * Severity Level 1 (Lowest)	33.920	32.887	32.017	31.768	31.749
Immature * Severity Level 5 (Highest)	159.462	158.128	157.021	157.005	157.004
Immature * Severity Level 4	72.478	71.132	70.018	69.946	69.937
Immature * Severity Level 3	32.912	31.777	30.841	30.633	30.613
Immature * Severity Level 2	24.333	23.245	22.351	22.082	22.055
Immature * Severity Level 1 (Lowest)	24.333	23.245	22.351	22.082	22.055
Premature/Multiples * Severity Level 5 (Highest)	115.833	114.548	113.499	113.406	113.398
Premature/Multiples * Severity Level 4	27.460	26.234	25.253	25.043	25.026
Premature/Multiples * Severity Level 3	14.214	13.255	12.482	12.044	12.001
Premature/Multiples * Severity Level 2	7.992	7.259	6.638	6.009	5.940
Premature/Multiples * Severity Level 1 (Lowest)	5.323	4.790	4.246	3.652	3.600
Term * Severity Level 5 (Highest)	91.593	90.463	89.524	89.335	89.320
Term * Severity Level 4	14.962	14.042	13.315	12.830	12.788
Term * Severity Level 3	5.857	5.300	4.767	4.150	4.092
Term * Severity Level 2	3.574	3.148	2.666	1.994	1.935
Term * Severity Level 1 (Lowest)	1.546	1.321	0.916	0.449	0.423
Age1 * Severity Level 5 (Highest)	253.927	252.583	251.467	251.462	251.464

TABLE 5—FINAL INFANT RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR—Continued

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Age1 * Severity Level 4	154.510	153.094	151.930	151.820	151.808
Age1 * Severity Level 3	33.920	32.887	32.017	31.768	31.749
Age1 * Severity Level 2	33.920	32.887	32.017	31.768	31.749
Age1 * Severity Level 1 (Lowest)	33.920	32.887	32.017	31.768	31.749
Age 0 Male	159.462	158.128	157.021	157.005	157.004
Age 1 Male	72.478	71.132	70.018	69.946	69.937

TABLE 6—HHS HCCS INCLUDED IN INFANT MODEL MATURITY CATEGORIES

Maturity category	HCC/description
Extremely Immature	Extremely Immature Newborns, Birth weight <500 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birth weight 500–749 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birth weight 750–999 Grams.
Immature	Premature Newborns, Including Birth weight 1,000–1,499 Grams.
Immature	Premature Newborns, Including Birth weight 1,500–1,999 Grams.
Premature/Multiples	Premature Newborns, Including Birth weight 2,000–2,499 Grams.
Premature/Multiples	Other Premature, Low Birth weight, Malnourished, or Multiple Birth Newborns.
Term	Term or Post-Term Singleton Newborn, Normal or High Birth weight.
Age 1	All age 1 infants.

TABLE 7—HHS HCCS INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

Severity category	HCC
Severity Level 5 (Highest)	Metastatic Cancer.
Severity Level 5	Pancreas Transplant Status/Complications.
Severity Level 5	Liver Transplant Status/Complications.
Severity Level 5	End-Stage Liver Disease.
Severity Level 5	Intestine Transplant Status/Complications.
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.
Severity Level 5	Respirator Dependence/Tracheostomy Status.
Severity Level 5	Heart Assistive Device/Artificial Heart.
Severity Level 5	Heart Transplant.
Severity Level 5	Congestive Heart Failure.
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders.
Severity Level 5	Lung Transplant Status/Complications.
Severity Level 5	Kidney Transplant Status.
Severity Level 5	End Stage Renal Disease.
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications.
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.
Severity Level 4	Mucopolysaccharidosis.
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age <2.
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis.
Severity Level 4	Aplastic Anemia.
Severity Level 4	Combined and Other Severe Immunodeficiencies.
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord.
Severity Level 4	Quadriplegia.
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.
Severity Level 4	Quadriplegic Cerebral Palsy.
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.
Severity Level 4	Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Severity Level 4	Respiratory Arrest.
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Severity Level 4	Acute Myocardial Infarction.
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic.
Severity Level 4	Major Congenital Heart/Circulatory Disorders.
Severity Level 4	Intracranial Hemorrhage.
Severity Level 4	Ischemic or Unspecified Stroke.
Severity Level 4	Vascular Disease with Complications.
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis.
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.
Severity Level 4	Chronic Kidney Disease, Stage 5.
Severity Level 4	Hip Fractures and Pathological Vertebral or Humerus Fractures.
Severity Level 4	Artificial Openings for Feeding or Elimination.
Severity Level 3	HIV/AIDS.
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis.

TABLE 7—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC
Severity Level 3	Opportunistic Infections.
Severity Level 3	Non-Hodgkin's Lymphomas and Other Cancers and Tumors.
Severity Level 3	Colorectal, Breast (Age <50), Kidney and Other Cancers.
Severity Level 3	Breast (Age 50+), Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.
Severity Level 3	Lipidoses and Glycogenosis.
Severity Level 3	Adrenal, Pituitary, and Other Significant Endocrine Disorders.
Severity Level 3	Acute Liver Failure/Disease, Including Neonatal Hepatitis.
Severity Level 3	Intestinal Obstruction.
Severity Level 3	Necrotizing Fasciitis.
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis.
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies.
Severity Level 3	Cleft Lip/Cleft Palate.
Severity Level 3	Hemophilia.
Severity Level 3	Disorders of the Immune Mechanism.
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders.
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord.
Severity Level 3	Paraplegia.
Severity Level 3	Spinal Cord Disorders/Injuries.
Severity Level 3	Cerebral Palsy, Except Quadriplegic.
Severity Level 3	Muscular Dystrophy.
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.
Severity Level 3	Hydrocephalus.
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease.
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders.
Severity Level 3	Specified Heart Arrhythmias.
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation.
Severity Level 3	Hemiplegia/Hemiparesis.
Severity Level 3	Cystic Fibrosis.
Severity Level 3	Fibrosis of Lung and Other Lung Disorders.
Severity Level 3	Pathological Fractures, Except of Vertebrae, Hip, or Humerus.
Severity Level 2	Viral or Unspecified Meningitis.
Severity Level 2	Thyroid, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.
Severity Level 2	Diabetes with Acute Complications.
Severity Level 2	Diabetes with Chronic Complications.
Severity Level 2	Diabetes without Complication.
Severity Level 2	Protein-Calorie Malnutrition.
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified.
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders.
Severity Level 2	Cirrhosis of Liver.
Severity Level 2	Chronic Pancreatitis.
Severity Level 2	Inflammatory Bowel Disease.
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders.
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders.
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders.
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.
Severity Level 2	Sickle Cell Anemia (Hb–SS).
Severity Level 2	Drug Psychosis.
Severity Level 2	Drug Dependence.
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.
Severity Level 2	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.
Severity Level 2	Seizure Disorders and Convulsions.
Severity Level 2	Monoplegia, Other Paralytic Syndromes.
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene.
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.
Severity Level 2	Chronic Ulcer of Skin, Except Pressure.
Severity Level 1 (Lowest)	Chronic Hepatitis.
Severity Level 1	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.
Severity Level 1	Thalassemia Major.
Severity Level 1	Autistic Disorder.
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder.
Severity Level 1	Multiple Sclerosis.
Severity Level 1	Asthma.
Severity Level 1	Chronic Kidney Disease, Severe (Stage 4).
Severity Level 1	Amputation Status, Lower Limb/Amputation Complications.
Severity Level 1	No Severity HCCs.

d. Cost-Sharing Reductions Adjustments (§ 153.320)

We proposed to continue including an adjustment for the receipt of cost-sharing reductions in the model to account for increased plan liability due to increased utilization of health care services by enrollees receiving cost-sharing reductions (induced demand) in all States where HHS operates risk adjustment. The proposed cost-sharing reductions adjustment factors for the 2019 benefit year were unchanged from those finalized in the 2018 Payment Notice. These adjustments would be effective for 2016, 2017, 2018, and 2019 risk adjustment, and would be multiplied against the sum of the demographic, diagnosis, and interaction factors, and enrollment and prescription drug utilization factors (for the adult models). We are finalizing the cost-sharing reductions adjustment factors as proposed. See Table 8 for the list of final cost-sharing reductions adjustments for the 2019 benefit year.

Comment: Commenters supported our proposal to use the same cost-sharing reductions adjustment induced demand factors as prior years, noting that the use of these factors would promote stability and certainty in the markets, and supported making updates in 2020 to the induced demand factors based on EDGE enrollee-level data. One commenter requested that HHS maintain the induced demand factors of 1.12 for wrap-around, premium assistance plans for Massachusetts, as established in the 2014 Payment Notice and used by Massachusetts for the 2014, 2015 and 2016 benefit years.

Response: We are finalizing the cost-sharing reductions adjustment induced demand factors as proposed. We anticipate proposing adjustments to the cost-sharing reductions adjustment induced demand factors in the annual HHS notice of benefit and payment parameters for the 2020 benefit year based on enrollee-level EDGE data. Consistent with the approach outlined in the final 2017 Payment Notice, we will continue to use cost-sharing reductions adjustment factors of 1.12 for all Massachusetts wrap-around plans in the risk adjustment transfers calculation, as all of Massachusetts' cost-sharing plan variations have actuarial values above 94 percent.

TABLE 8—COST-SHARING REDUCTIONS ADJUSTMENT

Household income	Plan AV	Induced utilization factor
Silver Plan Variant Recipients		
100–150% of FPL	Plan Variation 94%	1.12
150–200% of FPL	Plan Variation 87%	1.12
200–250% of FPL	Plan Variation 73%	1.00
>250% of FPL	Standard Plan 70%	1.00
Zero Cost-Sharing Recipients		
<300% of FPL	Platinum (90%)	1.00
<300% of FPL	Gold (80%)	1.07
<300% of FPL	Silver (70%)	1.12
<300% of FPL	Bronze (60%)	1.15
Limited Cost-Sharing Recipients		
>300% of FPL	Platinum (90%)	1.00
>300% of FPL	Gold (80%)	1.07
>300% of FPL	Silver (70%)	1.12
>300% of FPL	Bronze (60%)	1.15

e. Model Performance Statistics (§ 153.320)

To evaluate model performance, we examined each model's R-squared statistic and predictive ratios. The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The predictive ratios measure the predictive accuracy of a model for different validation groups or subpopulations. The predictive ratio for each of the HHS risk adjustment models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The predictive ratio represents how well the model does on average at predicting plan liability for that subpopulation. A subpopulation that is predicted perfectly would have a predictive ratio of 1.0. For each of the HHS risk adjustment models, the R-squared statistic and the predictive ratios are in the range of published estimates for concurrent risk adjustment models.[17] Because we are blending the coefficients from separately solved models based on 2014 and 2015 MarketScan® data and 2016 enrollee-level EDGE data, we are publishing the R-squared statistic for each model and benefit year separately to verify their statistical validity. The R-squared statistic for each model is shown in Table 9.

[17] Winkleman, Ross and Syed Mehmud. ''A Comparative Analysis of Claims-Based Tools for Health Risk Assessment.'' Society of Actuaries. April 2007.

TABLE 9—R-SQUARED STATISTIC FOR FINAL HHS RISK ADJUSTMENT MODELS

Risk adjustment model	R-squared statistic		
	2014 MarketScan®	2015 MarketScan®	2016 Enroll-level EDGE
Platinum Adult	0.4221	0.4212	0.4283
Platinum Child	0.293	0.3314	0.3099
Platinum Infant	0.3284	0.3329	0.3239
Gold Adult	0.4179	0.4164	0.4228
Gold Child	0.2883	0.3269	0.3053
Gold Infant	0.3264	0.3309	0.3201
Silver Adult	0.4143	0.4123	0.4181
Silver Child	0.2841	0.3227	0.3013
Silver Infant	0.325	0.3295	0.317
Bronze Adult	0.4117	0.4095	0.4152
Bronze Child	0.2805	0.3188	0.2978
Bronze Infant	0.3247	0.3292	0.3154
Catastrophic Adult	0.4115	0.4094	0.4145
Catastrophic Child	0.2803	0.3186	0.2971
Catastrophic Infant	0.3247	0.3292	0.3151

f. Overview of the Payment Transfer Formula (§ 153.320)

i. Accounting for High-Cost Risk Pool in the Transfer Formula

We previously defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule. In the 2014 Payment Notice, we combined those concepts into a risk adjustment payment transfer formula. Risk adjustment transfers (total payments and charges including high-cost risk pool payments and charges) will be calculated after issuers have completed risk adjustment data reporting. The payment transfer formula includes a set of cost adjustment terms that require transfers to be calculated at the geographic rating area level for each plan (that is, HHS will calculate separate transfer amounts for each rating area in which a plan operates).

The risk adjustment transfer formula generally calculates the difference between the revenues required by a plan, based on the health risk of the plan's enrollees, and the revenues that a plan can generate for those enrollees. These differences are compared across plans in the State market risk pool and converted to a dollar amount based on the Statewide average premium. Thus, each plan in the risk pool receives a risk adjustment payment or charge designed to compensate for risk for a plan with average efficiency. Scaling the risk adjustment transfers by the Statewide average premium, as opposed to, for example, the plan's own premium, minimizes issuers' ability to manipulate their transfers by adjusting their own plan premiums, and results in a calculation of equal payments and charges, ensuring that risk adjustment transfers for the entire market sum to zero.

In the absence of additional funding, we established, through notice and comment rulemaking,[18] risk adjustment as a budget neutral program in order to provide certainty to issuers regarding risk adjustment payments and allow them to set rates based on those expectations. Adopting an approach that would not result in balanced payments and charges would create considerable uncertainty for issuers regarding the proportion of risk adjustment payments they could expect to receive from the Federal government. Additionally, in establishing the HHS-operated risk adjustment program, HHS could not have relied on the potential availability of general appropriation funds without creating uncertainty for issuers in the amount of risk adjustment payments they could expect, or reducing funding available for other programs. Relying on each year's budget would have required HHS to delay setting the parameters for any risk adjustment payment proration rates well after the plans were in effect for the applicable benefit year. HHS also would not have been able to rely on any potential State budget appropriations for States that elected to operate a State-based risk adjustment program as such funds would not have been available for purposes of administering the HHS-operated risk adjustment program. Without the adoption of a budget neutral framework, HHS would have needed to assess a charge, or otherwise collect additional funds, or prorate payments based on the charges collected to balance the risk adjustment transfers. This uncertainty would conflict with the overall goals of the risk adjustment program: to stabilize premiums and reduce incentives for issuers to avoid enrolling individuals with higher than average actuarial risk.

The State payment transfer formula in the HHS risk adjustment methodology is designed to provide a per member per month (PMPM) transfer amount. The PMPM transfer amount derived from the State payment transfer formula would be multiplied by each plan's total billable member months for the benefit year to determine the total payment due to or charge owed by the issuer for that plan in a rating area. The total payment or charge is thus calculated to balance the State market risk pool in question.

In addition to the total charge or payment assessed for an issuer in a State market risk pool based on plan liability risk scores, in the 2018 Payment Notice, we added to the risk adjustment methodology additional transfers that would reflect the payments and charges assessed with respect to the high-cost risk pool. To account for costs associated with exceptionally high-risk enrollees, we added transfer terms (a payment term and a charge term) that would be calculated separately from the State transfer formula in the HHS risk adjustment methodology. Beginning for the 2018 benefit year, we added one term that reflects 60 percent of costs above $1 million ($HRP_i$, in the total plan transfer calculation described below), and another term that reflects a percent of premium adjustment to fund the high-cost risk pool and maintain the

[18] See, for example, Standards Related to Reinsurance, Risk Corridors and Risk Adjustment. Proposed Rule, 76 FR 41938 (July 15, 2011); Standards Related to Reinsurance, Risk Corridors and Risk Adjustment. Final Rule, 77 FR 17232 (March 23, 2012); and HHS Notice of Benefit and Payment Parameters for 2014. Final Rule, 78 FR 15441 (March 11, 2013).

balance of payment and charges within the risk adjustment program. The percent of premium adjustment factor applied to a plan's total premium amounts results in the same adjustment as a percent of PMPM premium adjustment factor applied to a plan's PMPM premium amount and multiplied by the plan's number of billable member months. For this calculation, we will use a percent of premium adjustment factor that is applied to each plan's total premium amounts, rather than the percent of PMPM premium adjustment factor described in 2018 Payment Notice and the proposed rule, for simplicity; and, as detailed above, we note that the mathematical outcome is the same. The percent of premium adjustment factor ($HRPC_m$) is determined based on the sum of payments for the high-cost risk pool enrollees divided by the sum of premiums in the respective high-cost risk pool market (m), nationally—one for the individual market, including catastrophic, non-catastrophic and merged market plans, and another for the small group market. The percent of premium adjustment factor is multiplied by the plan's total premium ($HRPC_m \cdot P_i$).

For the 2019 benefit year, we are finalizing the proposed policy to maintain this adjustment to the risk adjustment transfers with the threshold of $1 million and a coinsurance rate of 60 percent, as finalized for the 2018 benefit year.

Comment: In addition to the comments discussed above, one commenter requested that the high-cost risk pool adjustment factors be included in the risk adjustment formula.

Response: We have included a calculation for the total plan transfer amount below to illustrate the inclusion of the high-cost risk pool adjustment terms in the HHS risk adjustment methodology. As noted above, these terms will be applied within the high-cost risk pool markets nationally—one for the individual market, including catastrophic, non-catastrophic and merged market plans, and another for the small group market. We are finalizing the high-cost risk pool adjustment parameters for the 2019 benefit year as proposed.

ii. Administrative Cost Reduction to Statewide Average Premium

Additionally, we proposed to continue the policy finalized in the 2018 Payment Notice to reduce the Statewide average premium, the cost scaling factor in the risk adjustment transfer formula, by 14 percent to account for the proportion of administrative costs that do not vary with claims for the 2019 benefit year and future benefit years until changed in rulemaking. As a note, we have previously defined the cost scaling factor, or the Statewide average premium term, as the sum of average premium per member month of plan (P_i) multiplied by plan i's share of Statewide enrollment in the market in the risk pool (s_i). For the 2019 benefit year, the Statewide average premium, which will also be used for the transfer calculation for the 2018 benefit year, will be adjusted to remove a portion of the administrative costs as follows:

$$\bar{P}_S = (\Sigma_i(s_i \cdot P_i)) * 0.86$$

Where:

s_i = plan i's share of Statewide enrollment in the market in the risk pool;

P_i = average premium per member month of plan i.

We are finalizing the policy to reduce the Statewide average premium in the risk adjustment formula by 14 percent, as proposed, for the 2019 benefit year and future benefit years until changed in rulemaking.

Comment: Most commenters supported our proposal to continue to remove a portion of the administrative costs from the Statewide average premium factor of the risk adjustment transfer formula. Other commenters requested HHS publish the methodology used to create the 14 percent reduction from the MLR data. One commenter suggested HHS increase the reduction to 16 percent and another commenter requested HHS set the 14 percent reduction as the floor. Another commenter suggested HHS should set the factor closer to the market average of administrative costs, or allow the level to vary with issuers' claims experience.

Response: As we noted in the 2018 Payment Notice, we analyzed administrative and other non-claims expenses, including quality improvement expenses, taxes and fees, and non-claims costs, in the MLR Annual Reporting Form, and estimated, by category, the extent to which the expenses varied with claims. We compared those expenses to the total costs that issuers finance through premiums, including claims, administrative expenses, and taxes, netting out claims costs financed through cost-sharing reductions payments. We compared these expenses to total costs, rather than directly to premiums, to ensure that the estimated administrative cost percentage was not distorted by under- or over-pricing during the years for which MLR data are available. Using this methodology, we determined that the mean administrative cost percentage that does not vary with claims is 14 percent. We continue to believe that this percentage represents the mean administrative cost percentage that does not vary with claims in the individual and small group markets, and represents a reasonable percentage of administrative costs on which risk adjustment transfers should not be calculated. Based on this analysis, we are finalizing the policy as proposed to reduce the Statewide average premium factor of the risk adjustment formula by 14 percent. Allowing the factor to vary with claims experience could lead to gaming and risk selection, as issuers with lower risk would receive lower charges if their administrative costs are relatively higher. Therefore, we will continue to reduce the Statewide average premium factor of the risk adjustment formula by the same percentage for all issuers.

iii. State Flexibility

The HHS risk adjustment payment transfer formula generally transfers amounts from issuers with lower than average actuarial risk to those with higher than average actuarial risk. Risk adjustment is widely used in health insurance markets, and is recognized as a critical measure in mitigating the effects of adverse selection, ensuring financial viability of plans that enroll a higher proportion of high-risk enrollees, and fostering competitive health insurance markets. The State transfer formula in the HHS-operated risk adjustment program is scaled with the Statewide average premium in the applicable State market. In the 2018 Payment Notice, we noted that compared to other scaling factors, such as plans' own premiums, our analyses found that the Statewide average premium proves to be a more appropriate means of scaling the transfers for differences in relative actuarial risk, particularly in the context of a budget-neutral system. As noted in the above section, beginning with the 2018 benefit year, we also adopted an administrative cost adjustment to the Statewide average premium to remove a portion of administrative costs that did not vary based on claims differences from the Statewide average premium and base the transfers on the portion of the premiums that vary with claims.[19] We continue to believe the Statewide average premium, as adjusted, is a reasonable metric to measure the costs of adverse selection. Based on our experience operating the risk

[19] 81 FR 94099, 94100. (December 22, 2016). Available at *https://www.gpo.gov/fdsys/pkg/FR-2016-12-22/pdf/2016-30433.pdf.*

adjustment program, HHS has become aware that certain issuers, including some new, rapidly growing, or smaller issuers, owed substantial risk adjustment charges that they did not anticipate. HHS has had a number of discussions with issuers and State regulators on ways to encourage new participation in the health insurance markets and mitigate the effects of substantial risk adjustment charge amounts. We believe that a robust risk adjustment program that addresses concerns of risk selection is critical to the proper functioning of health insurance markets. However, we recognize that States are the primary regulators of their insurance markets. In the May 2016 Interim Final Rule,[20] HHS recognized some State regulators' belief that reducing the magnitude of risk adjustment charge amounts could be beneficial to the insurance markets in their States. For some States, an adjustment to risk adjustment transfers calculated under the HHS-operated risk adjustment program might more precisely account for cost differences attributable to adverse selection in the respective State market risk pools. We encouraged States to examine whether any local approaches under State legal authority are warranted to help ease the transition for new entrants to the health insurance markets and mitigate the effects of large risk adjustment charge amounts. In the small group market, employers select the plans offered to their employees and often pay a significant portion of employees' premiums to encourage enrollment. Depending on the participation rules and market dynamics within a particular State, risk selection can be significantly less in a State's small group market compared to its individual market. The HHS methodology calculates relative risk scores between issuers in a State market, and in the case of the small group market, the differences between risk scores for issuers within State markets are generally smaller, leading to a smaller magnitude of risk adjustment transfers in the small group market as compared to the individual market. Certain States have opined that the HHS risk adjustment methodology, which is calibrated on a national dataset and does not take into account the effect of State-specific laws and rating rules, in some circumstances may not precisely account for risk differences for their particular State. We note that States have the statutory authority to operate their own State risk adjustment program under a Federally certified alternate risk adjustment methodology and are free to exercise that authority to develop a risk adjustment program tailored to the markets in their State. However, we also believe that allowing certain State-specific adjustments to the HHS risk adjustment methodology can account for the effect of State-specific rules without the necessity for States to undertake operation of their own risk adjustment program.

In the case of small group markets, where States can demonstrate that the differential risk profiles observed in the small group market plans in that State are attributable to factors other than systematic risk selection, and adverse selection risk is mitigated by the small group market dynamics, such as those described above, we proposed to permit States' primary insurance regulators to request a percentage reduction in the calculation of the risk adjustment transfer amounts in the small group market in their State, beginning for the 2019 benefit year.

We proposed that HHS would require any State that seeks this flexibility to submit its proposal for an adjustment to the Statewide average premium in the small group market within 30 calendar days after publication of the proposed HHS notice of benefit and payment parameters for the applicable benefit year, in order to permit issuers to incorporate any such adjustment into their proposed rates. In order to promote transparency and solicit feedback from consumers and stakeholders on the proposed reductions to the HHS risk adjustment transfer formula, we proposed HHS would publish the requested State reduction percentages for public comment in guidance while it begins its initial review of the State requests. We proposed that HHS would then make final determinations on State requests by March 1 of the benefit year prior to the applicable benefit year, in time for issuers' initial rate setting deadline. The proposed timing of the State adjustment request, publication of HHS guidance setting forth the requested State reduction percentages, public notice and comment period and HHS approval process would permit plans to incorporate approved adjustments in their rates for the applicable benefit year.

Under the proposal, HHS would consider requests from State regulators to reduce the calculation of the Statewide average premium used in the HHS risk adjustment transfer formula in the small group market by up to 50 percent for the applicable benefit year. We sought comment on all aspects of this proposal for the small group market, including the size of the reduction, the timing of the request submission, what evidence States should be required to provide, and what procedural requirements should be established.

We also sought comment on whether we should establish a similar process through which States could request a reduction to the calculation of risk adjustment transfers in the individual market. Although adverse selection in the individual market is not mitigated by group enrollment or minimum participation requirements as is the selection in the small group market, we recognized that a State may believe the HHS risk adjustment methodology, which is calibrated on a national dataset, may not precisely account for relative actuarial risk differences in its individual market risk pool. We sought comment on whether, if a State can demonstrate such a difference in calculated relative actuarial risk, we should reduce States' administrative burden in operating its own risk adjustment program by allowing some flexibility in the HHS risk adjustment methodology to the extent permissible under the statute. Therefore, we sought comment on what individual market features would justify such a reduction, and what additional submissions a State should provide in order to justify such a departure for that market.

We recognize that it is possible the HHS risk adjustment methodology, which is calibrated on a national dataset and does not take into account State-specific rules or market dynamics, may not precisely account for relative actuarial risk differences in certain States' individual, small group or merged markets, and those State-specific rules or other relevant factors could support a reduction to transfers in that State's individual, small group or merged market. To accommodate situations where there may be such differences in State factors compared to the national norm, HHS is finalizing the policy to provide States the flexibility to request a reduction to the otherwise applicable risk adjustment transfers in the individual, small group or merged market by up to 50 percent with some modifications, outlined below, in response to comments. In States that request a reduction to transfers, the reduction percentage up to 50 percent, if approved by HHS, would be applied to the plan PMPM payment or charge transfer amount (T_i in the State transfer formula below), beginning with the 2020 benefit year. We are amending § 153.320 to add a new paragraph (d) to capture this State flexibility to request

[20] 91 FR 29146, 29152. (May 11, 2016). Available at *https://www.gpo.gov/fdsys/pkg/FR-2016-05-11/pdf/2016-11017.pdf.*

reduction to transfers in the individual, small group or merged market. States requesting such reductions must submit evidence and analysis to HHS identifying the State-specific rules or market dynamics that warrant an adjustment and demonstrating the actuarial risk differences in plans in the applicable State market are attributable to factors other than systematic risk selection, as well as substantiating the amount of the transfer reduction requested. For example, a State could submit evidence and analysis detailing the effect of a State rating rule that might lead to a portion of the State average premium that does not precisely reflect the cost of relative differences in actuarial risk in the individual, small group or merged market. The State request must specify in detail the State-specific rules or market dynamics that warrant an adjustment to the HHS risk adjustment methodology to more precisely account for the expected cost of relative risk differences in the State's individual, small group or merged market. Additionally, the State must submit evidence and analysis justifying the reduction percentage requested. To justify the amount of the transfer reduction requested, the State's evidence and analysis must explain how the requested transfer adjustment was determined by outlining the set of State-specific factors and the percentage reduction warranted to account for those factors in the State's market; or alternatively, it must demonstrate the requested reduction in risk adjustment payments would be so small for issuers who would receive risk adjustment payments, that the reduction would have a *de minimis* effect on the necessary premium increase to cover the affected issuer's or issuers' reduced payments. In the latter case, a State must demonstrate that the reduced risk adjustment payments would result in less than a 1 percent increase in the affected issuer's or issuers' premiums. We are adding paragraph (d)(1) to § 153.320 to specify the submission requirements for the State requests, as outlined above. We are also adding paragraph (d)(4) to specify that HHS will approve the State requests if, based on a review of the information submitted as part of the State request, along with other relevant factors, including the premium impact of the transfer reduction for the State market, and relevant public comments, HHS determines that the State-specific factors warrant an adjustment and the State request includes support justifying the percentage reduction requested or includes information demonstrating that the reduction to transfers would have a *de minimis* impact as described above. As reflected in paragraph (d)(4)(ii) to § 153.320, HHS may approve a reduction amount lower than that requested by the State if the supporting evidence and analysis do not fully support the percentage reduction requested. In response to commenters' concerns about market impacts on issuers with higher than average actuarial risk, HHS will assess other relevant factors, including the premium impact of the transfer reduction for the State market.

The approved reductions will be made on the calculated risk adjustment transfer amounts, rather than the Statewide average premium as proposed, prior to the application of the high-cost risk pool adjustments (high-cost risk pool payment and charge amounts). Applying the reduction is simply a mathematical operation and applying it on the otherwise calculated transfer amounts will result in the same final transfer amount mathematically as if the reduction was applied to the Statewide average premium, but will simplify the process for submission, review and calculation of the reductions to transfers.

We are finalizing modified timelines and adding paragraphs (d)(2) and (d)(3) at § 153.320 to capture the timeframe for submission and publication of State requests to reduce transfers in the individual, small group and merged markets in response to comments. We are not finalizing this proposed policy for the 2019 benefit year, in order to accommodate the evidence and analysis required and to provide more time for the development and review of such requests. Additionally, we believe the requests should be published in the relevant benefit year's proposed HHS notice of benefit and payment parameters to seek comment from relevant stakeholders. As such, consistent with paragraph (d)(2), beginning with 2020 and future benefit years, States must submit requests with the supporting evidence and analysis by August 1st, 2 calendar years prior to the beginning of the applicable benefit year (for example, August 1, 2018, for the 2020 benefit year) to *RARIpaymentoperations@cms.hhs.gov* with the subject ''[Insert applicable benefit year] State request to reduce risk adjustment transfers.'' This modified timeline responds to comment received and provides States the opportunity to review the most recent year of risk adjustment transfers data in determining the requested percentage reduction to transfers and when submitting the supporting evidence. As outlined in paragraph (d)(3), we will publish the 2020 and future benefit year requests in the respective benefit year's proposed HHS notice of benefit and payment parameters and make the supporting evidence available to the public in order to seek public comment, and will publish any approved State reduction requests or denied State reduction requests in the respective benefit year's final HHS notice of benefit and payment parameters.

Comment: A few commenters supported providing States the flexibility to request transfer reductions in the individual, small group and merged markets, noting that the risk adjustment program has been a barrier to entry for issuers in certain States. These commenters stated such a reduction to transfers could enable issuer participation in the individual, small group and merged markets. Additionally, these commenters noted the expense of operating a State-based risk adjustment program limits States from establishing their own risk adjustment methodologies. A few State regulators noted their intent to consider the reduction and potential impacts for future benefit years, and requested ''off-cycle'' dialogues with HHS to consider such reductions.

Several commenters supported the reduction to transfers only for the small group market, noting that the adverse selection in the individual market requires the risk adjustment program to ensure competitive and stable markets. These commenters noted such a reduction to transfers would be detrimental to market stability in the individual market, with one commenter noting that unexpectedly large charges were a risk for issuers in the early years of the program and the markets have since stabilized. A few commenters noted that HHS should allow States to permit reductions in merged markets as well, while others noted this policy should not be made available in merged markets given the impact on individual market dynamics in the merged market States. Yet a few commenters suggested the flexibility be allowed across the individual, small group and merged markets. One commenter noted that such a reduction would be appropriate in the individual market as well to reduce carrier-specific transfers to adjust for administrative costs, limit distortions due to how many family members are counted toward premiums, or prevent perverse incentives to avoid care management or network variations that lower costs.

Other commenters did not support a reduction to the risk adjustment transfers, stating the reduction to

transfers would undermine affordability of plans with sicker patients. Commenters were also concerned that providing such reductions would encourage risk selection behavior by issuers, encourage risk segmentation in the markets, reduce effectiveness of the risk adjustment program, lead to higher premiums for small employers and consumers where issuers with higher than average risk are not adequately compensated for their risk, reduce choices for consumers even further, and destabilize the markets. Commenters stated the importance of the risk adjustment program in promoting competition in the individual, small group, and merged markets by mitigating the issuers' risk of adverse selection. Commenters noted that the risk adjustment methodology already adjusts for a multitude of State- and rating area-specific factors as the methodology calculates risk scores at the individual level, and transfers at the rating area level. A few commenters also noted that maintaining risk adjustment as is would become increasingly important, especially if HHS were to move forward with the EHB flexibilities discussed elsewhere in this rule, as issuers could enroll differential risk enrollees based on the EHBs offered. Commenters noted that if HHS finalizes the policy to permit requests for adjustments in the small group market, issuers would no longer have an incentive to enroll all types of employers and could target healthier employers in certain sized employers through marketing and other strategies. Additionally, commenters noted that if relative risk for health conditions in an individual State is substantially different than the national average, it is not clear that a reduction of 50 percent to risk adjustment transfers would be appropriate, and the State ought to consider developing its own risk adjustment model to address significant deviations in the State's risk profiles that deviate from the national average or use the section 1332 of PPACA waiver process to implement a reinsurance type program. Commenters agreed with HHS that the smaller magnitude of transfers in the small group market than in the individual market indicates the lower adverse selection risk in the small group market, but stated that the HHS risk adjustment program is properly calibrated for this lower risk of adverse selection in the small group market. Commenters noted that while employer contributions, employer choice of benefit plans, and participation rules mitigate selection in the small group market, the risk adjustment methodology appropriately accounts for these market differences because the lower adverse selection is reflected in the lower risk score differential. Commenters noted that Oliver Wyman, American Academy of Actuaries, and HHS's studies have all shown the risk adjustment program is working as intended in mitigating adverse selection. A few commenters also noted a study by Oliver Wyman [21] that suggested reducing transfers by up to 50 percent may make the risk adjustment program less effective in compensating plans with higher than average risk and would therefore increase issuers' risk selection incentives. Additionally, one commenter noted that the significant adjustments to the risk adjustment program being implemented for the 2017 and 2018 benefit years should be evaluated prior to making any additional changes.

Response: In certain State individual, small group or merged markets, it is possible that the HHS risk adjustment methodology, which is calibrated on a national dataset, may not reflect State-specific factors that could result in relative risk differences in the State's market(s) compared to the national norm. Such unique State rules or other relevant factors could support a reduction to the otherwise applicable risk adjustment transfers to more precisely account for the differences in relative actuarial risk in the State's individual, small group or merged market. We agree with commenters that, in such instances, allowing certain State-specific adjustments to the otherwise applicable transfers can tailor the HHS-operated risk adjustment program to the particularities of a State's individual, small group or merged market without requiring the State to undertake operation of its own risk adjustment program or pursue a section 1332 waiver to implement a reinsurance program. In those circumstances, in which States can provide evidence and analysis showing the State-specific rules or market dynamics that warrant an adjustment to the HHS risk adjustment methodology to more precisely account for the relative risk differences in the State's market, HHS will consider requests to reduce transfers beginning with the 2020 benefit year. We agree with commenters that the small group market features, such as employers' selection of plans, and minimum participation and contribution rules, that lead to lower risk of adverse selection compared to the individual market are addressed in the current HHS risk adjustment methodology. Therefore, a State requesting a reduction of up to 50 percent of transfers in its small group market must provide supporting evidence and analysis outlining the State-specific factors that warrant an adjustment to the HHS risk adjustment methodology to more precisely account for relative risk differences in that State market compared to the national norm, rather than demonstrating the factors that are addressed in the current methodology. States must also justify the amount requested by outlining how the percentage reduction would more precisely account for risk differences in the State's individual, small group or merged market or by demonstrating that the reduction in risk adjustment payments would have a *de minimis* effect on the necessary premium increase to cover the affected issuer or issuers' reduced payments. HHS will not approve State requests for reduction to transfers based on factors in the State's individual, small group or merged market that are addressed by the current HHS risk adjustment methodology.

We appreciate commenters' concerns about extending the flexibility to the individual or merged markets. We believe that those enrolled in the individual or merged markets typically have higher actuarial risk, risk selection, and risk segmentation in plan selection than those enrolled in the small group market, and risk adjustment transfers are particularly required in these markets to mitigate issuers' risk of adverse selection and incentives to avoid risk. However, we recognize that, just as with certain States' small group markets, it is possible that certain factors unique to the States' individual or merged market, such as State rating requirements, could support a reduction to transfers in that State market, and therefore are finalizing the State flexibility to request reduction to otherwise applicable risk adjustment transfers in the individual and merged markets as well. We note that guaranteed availability, guaranteed renewability, as well as the non-discrimination provisions at §§ 147.104(e), 147.110 and 156.125(a), provide protections against potential employment of marketing practices or benefit designs that have the effect of avoiding less healthy employer groups, discriminating based on health conditions, or otherwise discouraging enrollment of individuals with significant health needs. Finally, allowing for the State flexibility for the 2020 benefit year, will allow us to assess

[21] Available at *http://health.oliverwyman.com/transform-care/2017/11/risk_adjustment.html.*

the impact of the changes made to the risk adjustment program beginning for the 2017 and 2018 benefit years, and we intend to monitor the impact of the changes to the risk adjustment program. States will also have the opportunity to assess the effects of the risk adjustment model changes implemented for the 2017 benefit year prior to submitting any State requests to reduce transfers for the 2020 benefit year.

Comment: A few commenters noted the extent of the reduction seemed arbitrary or too high, and requested HHS explain how it chose the 50 percent adjustment threshold. Commenters also suggested that HHS should finalize a smaller percentage reduction if it finalizes the proposal. One commenter stated that it is equally likely that a State needs to increase the risk adjustment transfers and HHS ought to allow for this type of a request as well.

Response: We are clarifying that the adjustment applicable to a State individual, small group or merged market would not necessarily be 50 percent, but would be the amount, up to 50 percent, justified by the State request. HHS reviewed transfers, the potential impact of such a reduction on market premiums and the proportion of the transfers as a percent of issuers' payments when considering the appropriate threshold. We believe that an adjustment of up to 50 percent, justified by State-specific factors, represents a reasonable balance between adjustment for actuarial risk based on a national methodology and recognition of unique State-specific factors that suggest that actuarial risk difference is not precisely accounted for by the national methodology. In instances where a State believes that an increase to risk adjustment transfers would be appropriate, State regulators under their own State authority could take actions outside of this flexibility to ease the transition for new entrants and/or mitigate the effects of large risk adjustment transfers. States can also elect to establish and operate the PPACA risk adjustment program. Additionally, we do not believe that an increase to the transfers could be deemed necessary as the current methodology would be sufficient to calculate the transfers necessary to compensate for the relative actuarial risk differences scaled to the average cost for the State market.

Comment: Some commenters noted that States should be required to submit an actuarially certified report demonstrating the extent to which the transfers overstate differentials in uncompensated predicted risk, the method of estimating the requested adjustment factor, an attestation that the percent reduction requested results in a risk adjustment methodology that complies with Actuarial Standard of Practice (ASOP) 12, Risk Classification, and an assessment of adverse selection effects that may result from the implementation of the payment transfer reduction. A few commenters also suggested HHS require States to provide evidence that issuers with large charges in the risk adjustment program did not have issues related to coding, operational data submission, incorrect rate setting, or suboptimal provider contracting and medical expenses that contributed to their risk adjustment results rather than differences in the State risk pool compared to the national average.

Response: We agree with commenters that States should be required to submit evidence and analysis supporting the requests for reductions to transfers in the individual, small group or merged market, and therefore, are requiring that States requesting a reduction in risk adjustment transfers submit supporting evidence and analysis to HHS. We are requiring States to submit supporting evidence and analysis demonstrating the State-specific rules or relevant factors that warrant an adjustment to more precisely account for risk differences in the State's individual, small group or merged market. Additionally, we are requiring the States to justify the percentage reduction requested based on supporting evidence and analysis that demonstrate how the adjustment would accommodate the State-specific factors and more precisely account for risk differences in the State's individual, small group or merged market or how the reduction would have a *de minimis* effect on the percent of premium increase necessary to cover the reduced payments to the affected issuers. We considered but are not requiring States to submit actuarially certified reports, an attestation, or simulation of the potential effects of the requested reduction as part of their requests. We determined that to ensure issuers are adequately compensated for the actuarial risk of their enrollees and do not have incentives to avoid higher risk enrollees, the State regulators need to submit evidence and analysis demonstrating the State-specific factors that warrant an adjustment to more precisely account for the differences in actuarial risk in the State's market, and justifying the percent reduction requested based on the State factors or a *de minimis* effect. Additionally, HHS will publish the requests in the proposed rulemaking for the respective benefit year and make the supporting evidence publicly available for comment, and consider the relevant comments in its review. We note that the data integrity issues flagged by commenters are assessed during the EDGE server data quality and quantity assessments, as well as through the risk adjustment data validation program.

Comment: Commenters generally requested additional time for States to submit requests. Commenters noted that if HHS were to move forward with this proposal, the agency should consider implementing the policy in 2020, as this policy will affect small group policies that are offered starting on and after January 1, 2018, as small group plans are not offered on a calendar year basis, and quarterly rate filings, which would already be in effect, would adversely affect these plans. One commenter suggested HHS set the State request deadline at 30 days after the June 30, 2018 risk adjustment summary report or request State submissions for the 2020 benefit year before August 2018. Other commenters suggested HHS allow States to provide the requests and any supporting material 60 days or 75 days from the publication of the proposed rule. Most commenters agreed that HHS should provide an opportunity for comment for the issuers and other stakeholders in the States that make such requests before approving or denying the reduction. One commenter also noted States require additional time to develop their respective requests and issuers require additional time to communicate their position with State regulators than that allowed by the timing in the proposed rule.

Response: We appreciate commenters' suggestions regarding timing, and are finalizing modified timelines for States to request a reduction to the risk adjustment transfers in response to these comments. As discussed above, States will be permitted to request these adjustments to transfers beginning for the 2020 benefit year. We agree with commenters that small group market issuers may have already begun policies that would be affected by a reduction to transfers for the 2019 benefit year, and issuers may need additional time to incorporate changes and reflect any reduction to transfers in their rates. Additionally, for the individual, small group and merged markets, we also considered the amount of time State regulators would require to assemble the supporting evidence and analysis to justify their requests and to consider the annual HHS June 30th risk adjustment transfers calculation results in determining the State reduction request.

The timeframe we are adopting in response to comments requires States to submit the request by August 1st, 2 calendar years prior to the applicable benefit year which will allow States to submit documentation to satisfy the supporting evidence and analysis requirements in this rule and incorporate the most recent available year of HHS risk adjustment transfer results in the State's request. Additionally, we agree with commenters about the importance of providing issuers and stakeholders an opportunity to comment on the request and supporting evidence. As outlined in paragraph (d)(3) of § 153.320, HHS will publish the requests in the respective benefit year's proposed HHS notice of benefit and payment parameters and make the supporting evidence available to the public to seek comment from relevant stakeholders, and will publish any final approved or denied reduction amounts in the final HHS notice of benefit and payment parameters for the respective benefit year. The modified timelines and supporting evidence requirements finalized in this rule, including the delayed application of this policy until the 2020 benefit year, are intended to provide States, issuers and other stakeholders with sufficient opportunity to develop, submit and comment on these reduction requests prior to finalization of the HHS-operated risk adjustment methodology for the applicable benefit year.

Comment: A few commenters noted that New York has already taken action to reduce transfers under the State's authority, and requested clarification whether other States could continue to take steps under existing State authority. One commenter noted that the New York adjustment could be seen as permitting States to make adjustments without HHS approval and requested clarification that States making adjustments to the risk adjustment formula must first obtain approval from HHS under the risk adjustment program prior to implementing any State-specific adjustments.

Response: As we noted above, States are the primary regulators of their insurance markets, and as such, we encourage States to examine whether any local approaches under State legal authority are warranted to help ease the transition for new participants to the health insurance markets. States that take such actions and make adjustments do not generally need HHS approval as these States are acting under their own State authority and using State resources. However, the flexibility finalized in this rule involves a reduction to the risk adjustment transfers calculated by HHS and will require HHS review as outlined above.

iv. The Payment Transfer Formula

The finalized State payment transfer formula for the 2019 benefit year is unchanged from what was finalized in the 2014 Payment Notice (78 FR 15430 through 15434). We believe it useful to republish the formula in its entirety. Transfers (payments and charges) will be calculated as the difference between the plan premium estimate reflecting risk selection and the plan premium estimate not reflecting risk selection. The State payment transfer calculation that is part of the HHS risk adjustment payment transfer formula is:

$$T_i = \left[\frac{PLRS_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot PLRS_i \cdot IDF_i \cdot GCF_i)} - \frac{AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i)}\right] \bar{P}_s$$

Where:

$\bar{P}_S$ = Statewide average premium;
$PLRS_i$ = plan *i*'s plan liability risk score;
AV_i = plan *i*'s metal level AV;
ARF_i = allowable rating factor;
IDF_i = plan *i*'s induced demand factor;
GCF_i = plan *i*'s geographic cost factor;
s_i = plan *i*'s share of State enrollment;

The denominator is summed across all plans in the risk pool in the market in the State.

The difference between the two premium estimates in the State payment transfer calculation determines whether a plan pays a risk adjustment charge or receives a risk adjustment payment. The value of the plan average risk score by itself does not determine whether a plan would be assessed a charge or receive a payment—even if the risk score is greater than 1.0, it is possible that the plan would be assessed a charge if the premium compensation that the plan may receive through its rating (as measured through the allowable rating factor) exceeds the plan's predicted liability associated with risk selection. Risk adjustment transfers are calculated at the risk pool level, and catastrophic plans are treated as a separate risk pool for purposes of the risk adjustment transfer calculation, not including the national high-cost risk pool payments and charges. This resulting PMPM plan payment or charge is multiplied by the number of billable member months to determine the plan payment or charge based on plan liability risk scores for a plan's geographic rating area for the risk pool market within the State.

Beginning with the 2018 benefit year, the high-cost risk pool adjustment amount will be added to the plan transfers (payment or charge) to account for: (1) The payment term, representing the portion of costs above the threshold reimbursed to the issuer for high-cost risk pool payments (HRP_i), if applicable, and (2) the charge term, representing a percent of premium adjustment, which is the product of the high-cost risk pool adjustment factor ($HRPC_m$) for the respective national high-cost risk pool *m* (one for the individual market, including catastrophic, non-catastrophic and merged market plans, and another for the small group market), and the plan's total premiums (P_i). As we noted above, the percent of premium adjustment factor applied to a plan's total premium amounts results in the same adjustment as a percent of PMPM premium adjustment factor applied to a plan's PMPM premium amount and multiplied by the plan's number of billable member months. For this calculation, we will use a percent of premium adjustment factor that is applied to each plan's total premium amounts, rather than the percent of PMPM premium adjustment factor for simplicity; and reiterate that the mathematical outcome is the same.

With the high-cost risk pool adjustment amount, the total plan transfers would be calculated as the product of the plan PMPM transfer amount (T_i) multiplied by the plan's billable member months (M_i), plus the high-cost risk pool adjustments. The total plan transfer (payment or charge) amounts under the HHS risk adjustment payment transfer formula would be calculated as follows:

$$Total\ transfer_i = (T_i \cdot M_i) + HRP_i - (HRPC_m \cdot P_i)$$

Where:

T_i = Plan *i*'s PMPM transfer amount;
M_i = Plan *i*'s billable member months;
HRP_i = Plan i's total high-cost risk pool payment;
$HRPC_m$ = High-cost risk pool percent of premium adjustment factor for the respective national high-cost risk pool *m;*
P_i = Plan *i*'s total premium amounts.

In States that requested a reduction to transfers in the individual, small group or merged market, the reduction

percentage up to 50 percent, if approved by HHS for the applicable benefit year beginning with the 2020 benefit year, would be applied to the plan PMPM payment or charge transfer amount (T_i). This potential reduction to the PMPM transfer amounts is not shown in the risk adjustment transfer formula above.

g. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (§ 153.630)

HHS will conduct risk adjustment data validation under § 153.630 in any State where HHS is operating risk adjustment on a State's behalf.[22] The purpose of risk adjustment data validation is to ensure issuers are providing accurate high-quality information to HHS, which is crucial for the proper functioning of the risk adjustment program. Risk adjustment data validation consists of an initial validation audit and a second validation audit. Under § 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation audit entity. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to its initial validation auditor for data validation. Set forth below are final amendments and clarifications to the risk adjustment data validation program in light of experience and feedback from issuers during the first pilot year.

i. Payment Adjustments for Error Rates

Under § 153.350(c), HHS may adjust risk adjustment payments and charges to all issuers of risk adjustment covered plans based on adjustments to the average actuarial risk of a risk adjustment plan due to errors discovered during risk adjustment data validation. Under the original risk adjustment data validation payment adjustment approach, all issuers of risk adjustment covered plans would receive an adjustment to payment transfers in the subsequent benefit year based on risk adjustment data validation audit results and using the audit-confirmed, issuer-specific risk score error rate. However, we believe that some variation and error should be expected in the compilation of data for risk scores, because providers' documentation of enrollee health status varies across provider types and groups. Our experiences with the Medicare Advantage risk adjustment data validation program and the HHS risk adjustment data validation pilot for the 2015 benefit year reinforce this belief.

To avoid adjusting all issuers' risk adjustment payments for expected variation and error, we proposed evaluating material statistical deviation in error rates beginning with 2017 benefit year risk adjustment data validation. In the proposed rule, we explained that we were considering adjusting an issuer's risk score only when the issuer's error rate materially deviates from a statistically meaningful value, such as the central tendency (a mean or typical value) of errors, nationally. When an error rate materially deviates from the central tendency, we proposed to apply the difference between the mean error rate or the confidence interval around the population's central tendency and the calculated error rate instead of the full error rate. If all error rates in a State risk pool do not materially deviate from the national central tendency of error rates, we proposed to not apply any adjustments to issuers' risk scores for that benefit year in the respective State risk pool.

We also noted that alternatively, HHS could evaluate error rates within each HCC, or groups of HCCs, and then only apply error rates to outlier issuers' risk scores within each HCC or group of HCCs. In evaluating the ''error rate'' of HCCs, or groups of HCCs, we mean the probability of an assigned HCC being found to be incorrect based on the risk adjustment data validation audit, or a ''failure rate.'' The percent of the EDGE risk score that is incorrect due to audit findings (that is, due to HCCs that could not be validated through audit), we consider to be the issuer's risk score error rate. For example, an issuer could have a 50 percent failure rate for an HCC, in that two of four instances of the HCC on EDGE could not be validated. The impact of HCC failure rates on an issuer's error rate will then depend on the magnitude of the missing HCC's coefficient and the incidence of that HCC in the audit sample.

We believe the implementation of any of the alternative evaluations and subsequent adjustments we proposed would streamline the risk adjustment data validation process, improve issuers' ability to predict risk adjustment transfers, and promote confidence and stability in the budget-neutral payment transfer methodology, while ensuring the integrity and quality of data provided by issuers.

We are finalizing the approach described above of using failure rates specific to HCC groups and subsequently adjusting the issuer's risk score when the issuer's failure rate for a group of HCCs is statistically different from the weighted mean failure rate, or total failure rate, for that group of HCCs for all issuers that submitted initial validation audits. We are selecting this approach based on comments received, which generally were more supportive of the HCC or HCC-grouping methodology for evaluating failure rates than an approach under which we would calculate a national overall error rate. Additionally, we believe determining outlier failure rates based on HCC groups mitigates gaming concerns raised by commenters in using a national error rate, and mitigates commenters' sample size concerns in using HCC-specific failure rates. Our simulations of failure rates by HCC group suggest that such an approach yields a more equitable measure to evaluate statistically different HCC failure rates affecting an issuer's error rate than an approach based on an overall failure rate, which may overly adjust issuers with abnormal distributions of certain HCCs due to their underlying populations rather than differences due to errors in diagnoses codes. Illustrations of the methodology we will use to evaluate failure rate differences by HCC group, calculate error rates based on failure rates, and apply error rates to risk scores are provided below.

Using data from the 2017 benefit year risk adjustment data validation, HHS will first calculate the failure rate for each HCC in issuers' initial validation audit samples as:

$$FR^h = 1 - \frac{Freq_IVA^h}{Freq_EDGE^h}$$

Where:

$Freq_EDGE^h$ is the frequency of HCC code h occurring on EDGE, which is the number of sampled enrollees recording HCC code h on EDGE.

$Freq_IVA^h$ is the frequency of HCC code h occurring in IVA results, which is the number of sampled enrollees with HCC code h on in IVA results.

FR^h is the failure rate of HCC code h.

HHS will then create three HCC groups based on the HCC failure rates derived in the calculation above. These HCC groups will be determined by first ranking all HCC failure rates and then dividing the rankings into three groups, weighted by total observations or frequencies, of that HCC across all issuers' initial validation audit samples, to assign each unique HCC in the initial validation audit samples to a high, medium, or low failure rate group with an approximately even number of observations in each group. That is, each HCC group may have an unequal number of unique HCCs, but the total

[22] Starting with the 2017 benefit year, no State has elected to operate a risk adjustment program. Therefore, HHS operates risk adjustment in all States.

observations in each group should be approximately equal based on total observations of HCCs reflected in EDGE data for all issuers' initial validation audit sample enrollees, to prevent small sample sizes for an HCC group for any issuer.

HHS will then compare each issuer's failure rate for each HCC group based on the number of HCCs validated in the initial validation audit, compared to the number of HCCs recorded on EDGE within that HCC group for the initial validation audit sample enrollees. The issuer's HCC group failure rate will be compared to the weighted mean failure rate, or total failure rate, for that HCC group. We calculate an issuer's HCC group failure rate as:

$$GFR_i^G = 1 - \frac{Freq_IVA_i^G}{Freq_EDGE_i^G}$$

Where:

$Freq_EDGE_i^G$ is the number of HCCs in group G in the EDGE sample of issuer i.

$Freq_IVA_i^G$ is the number of HCCs in group G in the IVA sample of issuer i.

GFR_i^G is i's group failure rate for the HCC group G.

We will also calculate the weighted mean failure rate and the standard deviation of each HCC group as:

$$\mu^*(GFR^G) = 1 - \frac{\sum Freq_IVA_i^G}{\sum Freq_EDGE_i^G}$$

$$Sd(GFR^G) = \sqrt{\frac{\sum_i Freq_EDGE_i^G * \left(GFR_i^G - \mu(GFR^G)\right)^2}{\sum_i Freq_EDGE_i^G}}$$

Where:

$\mu(GFR^G)$ is the weighted mean of GFR_i^G of all issuers for the HCC group G weighted by all issuers' sample observations in each group.

$Sd(GFR^G)$ is the standard deviation of GFR_i^G of all issuers for the HCC group G.

If an issuer's failure rate for an HCC group falls outside the confidence interval for the weighted mean failure rate for the HCC group, the failure rate for the issuer's HCCs in that group would be considered an outlier. We will use a 1.96 standard deviation cutoff, for a 95 percent confidence interval, to identify outliers. To calculate the thresholds to classify an issuer's group failure rate as outliers or not, the lower and upper limits are computed as:

$LB^G = \mu(GFR^G) - sigma_cutoff * Sd(GFR^G)$

$UB^G = \mu(GFR^G) + sigma_cutoff * Sd(GFR^G)$

Where:

sigma_cutoff is the parameter used to set the threshold for the outlier detection as the number of standard deviations away from the mean.

LB^G, UB^G are the lower and upper thresholds to classify issuers as outliers or not outliers for group G.

When an issuer's HCC group failure rate is an outlier, we will reduce (or increase) each of the applicable initial validation audit sample enrollees' HCC coefficients by the difference between the outlier issuer's failure rate for the HCC group and the weighted mean failure rate for the HCC group. Specifically, this will result in the sample enrollees' applicable HCC risk score components being reduced (or increased) by a partial value, or percentage, calculated as the difference between the outlier failure rate for the HCC group and the weighted mean failure rate for the applicable HCC group. The adjustment amount for outliers will be the distance between issuer i's Group Failure Rate GFR^i_G and the weighted mean $\mu(GFR^G)$, calculated as:

$$\text{If } GFR_i^G > UB^G \text{ or } GFR_i^G < LB^G:$$

$$\text{Then } Flag_i^G = \text{"}outlier\text{"} \text{ and } Adjustment_i^G = GFR_i^G - \mu(GFR^G)$$

$$\text{If } GFR_i^G \leq UB^G \text{ and } GFR_i^G \geq LB^G:$$

$$\text{Then } Flag_i^G = \text{"}not\ outlier\text{"} \text{ and } Adjustment_i^G = 0$$

Where:

$Flag_i^G$ is the indicator if issuer *i*'s group failure rate for group *G* locates beyond a calculated threshold that we are classifying issuers into "outliers" or "not outliers" for group *G*.

$Adjustment_i^G$ is the calculated adjustment amount to adjust issuer *i*'s EDGE risk scores for all sampled HCCs in group *G*.

The adjustment to an enrollee's total risk score is calculated as the ratio of the total adjusted risk score for individual HCCs to the total risk score components for individual HCCs. For example, if an issuer has one enrollee with the HIV/AIDS HCC and the issuer's HCC group adjustment rate is 10 percent (the difference between the issuer's group failure rate and the weighted mean failure rate) for the HCC group that contains the HIV/AIDS HCC, the enrollee's HIV/AIDS coefficient would be reduced by 10 percent. We calculate the total adjustment amount across all HCCs per enrollee as:

$$Adjustment_{i,e} = \frac{\sum_{hcc}\left(RS_{i_e}^{hcc,G} * Adjustment_i^G\right)}{\sum_{hcc}\left(RS_{i,e}^{hcc,G}\right)}$$

Where:

$RS_{i.e}^{hcc,G}$ is the risk score component of a single HCC (belonging to HCC group *G*) recorded on EDGE for enrollee *e* of issuer *i*.

$Adjustment_{i,e}$ is the calculated adjustment amount to adjust enrollee *e* of issuer *i*'s EDGE risk scores.

The adjusted risk score for enrollee *e* of issuer *i* is calculated as:

$AdjRS_{i,e} = EdgeRS_{i,e} * (1 - Adjustment_{i,e})$

Where:

$EdgeRS_{i,e}$ is the risk score for EDGE HCCs of enrollee *e* of issuer *i*.

$AdjRS_{i,e}$ is the adjusted risk score for sampled enrollee *e* of issuer *i*.

We will then calculate an issuer's error rate using the EDGE risk score and adjusted risk score for all enrollees in the sample (excluding enrollees with no HCCs). The weight w_e in the error rate calculation formula is obtained by the ratio of an enrollee's stratum size in the issuer's population to the number of sample enrollees in the same stratum as the enrollee, to extrapolate the sample adjusted risk scores and determine the issuer's risk score error rate. The formula to compute the error rate using the stratum weighted risk score for issuer *i* before and after the adjustment is shown as:

$$ErrorRate_i = 1 - \frac{\sum_e \left(w_e * AdjRS_{i,e}\right)}{\sum_e \left(w_e * EdgeRS_{i,e}\right)}$$

Where:

$$w_e = \frac{stratum\ size\ in\ population}{number\ of\ sample\ enrollees\ of\ the\ stratum}$$

$ErrorRate_i$ is the final error rate for issuer *i* based on sampled enrollees.

The risk score error rate would then be applied to the subsequent benefit year calculated plan level risk scores, to adjust the issuer's plan level risk scores before risk adjustment transfers are calculated, unless the issuer exited the market during or at the end of the benefit year being audited.[23]

Comment: Most commenters supported the proposal to only adjust issuers' risk scores if their failure or error rates materially deviate from a statistical mean, with some noting that this approach could help streamline risk adjustment data validation and increase market stability. A few commenters noted the complexity of the approach and requested more information on various aspects of the proposed approach, such as the definitions of material deviation and statistically meaningful value, the methodology that HHS would use to evaluate material deviation, the calculation of national or HCC-level error rates, and the sufficiency of the sample sizes under the HCC or group of HCCs approach.

Response: As outlined above, for the purposes of risk adjustment data validation, we will determine that an issuer's failure rate is statistically different if the issuer's failure rate for a particular HCC group is more than 1.96 standard deviations away from the weighted mean failure rate for the high, medium, or low HCC group. Issuers with outlier failure rates in a particular HCC group will then have their sample enrollee risk scores adjusted by the difference between the issuer's failure rate and the mean failure rate for that HCC group for all applicable HCCs in their sample enrollees' risk scores. We will not use an overall mean failure rate or error rate to determine outliers under the approach finalized in this rule. We believe that the HCC grouping approach described above, which utilizes three large HCC groupings, will mitigate the risk of an issuer having a small sample size for a particular HCC group. We also note that we intend to propose updates to the sampling methodology for the 2018 benefit year HHS-operated risk adjustment data validation initial validation audit samples in the 2020 Payment Notice.

Comment: One commenter supported the proposed application of the difference between the calculated error rate and the statistically meaningful value, instead of the full error rate, to the issuer's subsequent year risk score when material deviation occurs. One commenter opposed the proposal due to concerns that if the average failure rate is exceedingly high or increasing, it could encourage issuers to be less accurate over time in their risk adjustment data, as long as they are not outliers relative to other issuers. Another commenter expressed concerns that issuers within the calculated confidence interval would receive no adjustments, while issuers outside of the confidence interval would receive substantial and punitive adjustments.

Response: The primary purpose of determining statistically meaningful differences is to avoid the unwarranted application of risk score adjustments—that is, risk scores would be adjusted only when the issuers' failure rates are outside a range of statistically acceptable errors. We believe that statistically meaningful errors should be adjusted to the weighted mean failure rate of each HCC group. We are finalizing an approach under which, when an issuer's failure rate for its associated HCCs in one of the HCC groupings is statistically different than the mean for that grouping, HHS will adjust the sample enrollees' risk score component for that HCC group by the difference between the issuer's failure rate for the HCCs in that group and the weighted mean failure rate for the HCC group for all issuers that submitted initial validation audits. We will continue to evaluate this approach; however, we expect that as issuers and initial validation auditors gain additional experience performing risk adjustment data validation, HCC failure rates should improve and stabilize, rather than grow.

Comment: Several commenters recommended that HHS provide issuers with more transparency about the calculation of error rates, as well as benchmark national and State-level error rate data against which issuers could evaluate their performance relative to other issuers and in the context of this proposal. Two commenters suggested that HHS apply the proposed approach to the 2016 benefit year pilot results to illustrate how issuers' risk scores and payment transfers might be affected in future years.

Response: We appreciate the recommendations, and we intend to publish benchmark failure and error rate data based on the results of the 2016 benefit year data validation second pilot year. We also intend to provide additional information to issuers about risk score error rates based on 2016 benefit year risk adjustment data validation results, prior to implementation in 2017 benefit year risk adjustment data validation. In addition, illustrations of the methodology we will use to evaluate failure rate differences by HCC group, calculate error rates based on failure rates and apply error rates to risk scores are provided above.

Comment: Two commenters recommended that HHS continue to study failure rates by HCCs or groups of HCCs for a longer period of time before proceeding with this approach, and another commenter opposed the calculation of failure rates at the HCC or HCC group-level.

Response: We evaluated the HCC group-level and other proposed approaches using a simulation with underlying Medicare risk adjustment data validation failure rates, and we agree with commenters that additional data from HHS-operated risk adjustment data validation results in a payment adjustment year would be preferable. However, under the current error rate estimation and application policy for HHS-operated risk adjustment data

[23] See section III.B.2.g.ii. of this rule, for a discussion of changes being finalized with respect to payment adjustments for issuers that have exited the market.

validation, all issuers' risk scores and payment transfers would be adjusted, for any identified error, regardless of issuer size or distribution of HCCs in its enrollee population beginning with the 2017 benefit year data validation. We believe the approach being finalized in this rule will increase predictability of risk adjustment transfers for issuers, and improve our ability to identify statistically meaningful data discrepancies in the data validation process. By focusing on issuer errors that are statistically meaningful, we can adjust issuers' risk scores with confidence, as opposed to adjusting all issuers for any difference, significant or not, from EDGE data. As such, we believe implementing this approach as soon as possible ensures the most accurate payment adjustments and promotes stability and predictability of risk adjustment transfers.

Comment: A few commenters raised concerns that the calculation of a national average error rate could fail to account for State or regional variations in provider coding practices, and therefore result in harmful adjustments that could discourage new entrants in some States.

Response: We agree with commenters and believe the evaluation of failure rate deviation by groups of HCCs, based on HCC failure rates outlined above, rather than a single, national average failure rate for all HCCs, will mitigate the risk of adjustments due to errors or differences that can be explained by regional variation in provider documentation of enrollee health status. We will evaluate the impact of this approach on issuers across regions and States and consider adjustments in future years if there is evidence of regional bias in payment adjustments resulting from this policy.

Comment: One commenter requested that HHS conduct another pilot year prior to implementing payment adjustments, since data validation is still new for issuers in the commercial market.

Response: While we will continue to educate issuers about the HHS risk adjustment data validation process, we believe that it is necessary to use the results of data validation to adjust risk scores beginning with 2017 benefit year data validation to encourage issuers to continue to improve the accuracy of data used to compile risk scores and to preserve confidence in the HHS-operated risk adjustment program.

ii. Payment Adjustments for Issuers That Have Exited the Market

In the 2015 Payment Notice, we established that HHS will use a prospective approach to adjust risk scores and payment transfers based on the results of risk adjustment data validation. Specifically, HHS will apply the error rate calculated through the risk adjustment data validation process for the applicable benefit year to plan risk scores in the subsequent benefit year, and then make risk adjustment payment transfers based on adjusted plan average risk scores in that subsequent benefit year. However, in some cases, an issuer of a risk adjustment covered plan may have exited a State market during or at the end of the benefit year being audited and therefore would not have risk scores or payment transfers in the subsequent benefit year to which HHS could make adjustments.

As previously noted, the purpose of risk adjustment data validation is to promote confidence in the budget-neutral payment transfer methodology by ensuring the integrity and quality of data provided from issuers. HHS believes that the prospect of not receiving payment adjustments based on the results of risk adjustment data validation results could undermine these goals by eliminating the incentive for an exiting issuer to carefully and accurately submit risk adjustment data for its final benefit year in the market. Not only could this type of inaccuracy result in overpayments to the exiting issuer, it could also cause the other issuers in the market to be over or undercompensated for the actual risk of their enrollee populations. Therefore, we proposed that HHS would use the error rate derived from the risk adjustment data validation process to adjust the payment transfer for the issuer's final benefit year in the State market, which would be concurrent with the benefit year being audited, for issuers that exit a State market during or at the end of the benefit year being audited. Because risk adjustment transfers for a given benefit year are calculated and paid before the risk adjustment data validation process for that benefit year is completed, this approach would require HHS to make a retroactive (that is, post-transfer) adjustment to the issuer's payment transfer for its final benefit year and reallocate the adjusted transfer amount to the other issuers in the State market in that year.

We sought comment on this proposal to make these adjustments to payment transfers for issuers that have exited the market based on the results of risk adjustment data validation for the most recent benefit year in which they participated in risk adjustment. We are finalizing this policy as proposed, and we clarify that it will be effective beginning with the 2017 benefit year risk adjustment data validation. Therefore, for an issuer that exited a State market during or at the end of the 2017 benefit year who had a statistically meaningful error rate under the revised approach to payment adjustments finalized above in this rule, HHS would apply the risk score error rate to the issuer's 2017 benefit year risk score, and recalculate 2017 benefit year risk adjustment transfers for the affected State market risk pools. We note that, under this timeline, issuers that exited a State market during or at the end of 2017 benefit year have ample opportunity to review and correct data submitted to their EDGE servers that will be used to calculate risk scores for the 2017 benefit year.

Comment: The majority of commenters supported using the error rate derived from data validation for the most recent benefit year in which an exited issuer participated in risk adjustment to make an adjustment to exited issuers' risk adjustment transfers for their final benefit year in the State market, and to reallocate the adjusted amount to the other issuers in the State market in that year. Commenters agreed that a post-transfer adjustment, based on results of data validation for the most recent benefit year for which the issuer participated in risk adjustment, would reduce the risk of gaming by an issuer leaving a State market and ensure that other issuers remaining in the State market are not harmed by an exited issuer's incorrect or incomplete data. One commenter expressed concern that the adjustments for exited issuers would complicate payment transfers and requested that HHS provide additional guidance or create a forum with issuers to discuss which method would result in the least disruption to the data validation process over multiple years.

Response: We agree with commenters who supported a post-transfer adjustment for issuers who exit the market during or at the end of a given benefit year, and we are finalizing the policy as proposed. Adjusting an exited issuer's payment transfer will help ensure that an issuer with inaccurate or incomplete data does not benefit from this error and that other issuers in the State market are not harmed by it. We acknowledge that adjustments to final benefit year payment transfers for issuers that exited a State market could complicate the calculation of transfers; however, we believe the revised policy for error rate payment adjustments finalized above will help mitigate the potential complexity, because only exited issuers with statistically meaningful failure rates will receive

post-transfer adjustments. Furthermore, we believe the benefits associated with applying adjustments to exited issuers' payment transfers, based on the results of risk adjustment data validation for the most recent benefit year in which they participated in risk adjustment, outweigh the complexities. For State market risk pools where HHS determines that an issuer that exited the market will receive an adjustment to their risk adjustment transfer for their final benefit year in the market, we intend to provide all issuers in the affected prior year risk pool with the adjustments for exited issuers at the same time as adjustments for any issuers remaining in the market are made in the subsequent benefit year.

iii. 500 Billable Member Months

Numerous small issuers have expressed concern regarding the regulatory burden and cost associated with complying with the risk adjustment data validation program. HHS has previously considered these concerns and provided relief where possible. In the proposed rule, we proposed that, beginning with 2017 benefit year risk adjustment data validation, issuers with 500 billable member months or fewer that elect to establish and submit data to an EDGE server would not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results. We explained that we believe exempting issuers with 500 billable member months or fewer from the requirement to hire an initial validation auditor is appropriate because issuers of this size would have a disproportionately high operational burden for compliance with risk adjustment data validation. We noted that, beginning with 2018 benefit year risk adjustment data validation, these issuers would not be subject to random sampling under the materiality threshold discussed below, and would continue to not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results. We also explained that if the approach for payment adjustments for error rates outlined in the proposed rule were finalized, then it would be possible that no adjustment would occur for issuers below this threshold. We sought comments on the proposal, including the 500 billable member month threshold.

We are finalizing the exemption for issuers with 500 billable member months or fewer as proposed. We clarify that, consistent with the approach in the 2017 Payment Notice for the lower, separate risk adjustment default charge for small issuers, the determination of whether an issuer has 500 billable member months or fewer will be calculated Statewide (that is, combining an issuer's enrollment in a State's individual and small group markets in a benefit year).

Comment: A commenter agreed with the proposal, but suggested that issuers with 500 or fewer billable member months be excluded from risk adjustment data validation entirely. One commenter disagreed with the proposal stating that all issuers should be subject to audits for accountability. One commenter agreed with the proposal, but wanted an option for small issuers to be adjusted by a default error rate based on the issuer's parent company's aggregate or average error rate.

Response: HHS recognizes that issuers' company-level affiliations may vary in size considerably, but note that regardless of parent company size, issuers with 500 or fewer billable member months Statewide face a relatively large burden in complying with an initial validation audit where the initial validation audit sample would be the issuer's entire population. Consistent with the risk adjustment data validation error rate payment adjustment policy finalized above, we believe that only issuers with statistically meaningful errors should receive payment adjustments. We believe that the implementation of this policy provides similar relief to smaller issuers for whom audits would have a disproportionately high cost and who, due to small size, are unlikely to have a significant or material impact on adjustments to other issuers. We note that the risk adjustment data validation policies finalized in this rule result in issuers with 500 or fewer billable member months Statewide effectively being excluded from risk adjustment data validation, as they do not have to hire an initial validation auditor, submit initial validation audit results, or be subject to risk adjustment data validation payment adjustments.

iv. Materiality Threshold for Risk Adjustment Data Validation

In the 2018 Payment Notice, HHS implemented a materiality threshold for risk adjustment data validation to ease the burden of annual audit requirements for smaller issuers of risk adjustment covered plans. Specifically, we stated that issuers with total annual premiums at or below $15 million (calculated based on the premiums of the benefit year being validated) would not be subject to *annual* initial validation audit requirements, beginning with the 2017 benefit year, but would still be subject to an initial validation audit approximately every 3 years. HHS based the timeline for enforcement of the materiality threshold on the expectation that we would begin making payment adjustments based on the results of the 2016 benefit year risk adjustment data validation, effectively requiring all issuers of risk adjustment covered plans to participate in the first benefit year for which risk adjustment payments are adjusted. However, in light of our subsequent decision to convert the 2016 benefit year to another pilot year,[24] in the proposed rule, we proposed to postpone application of the materiality threshold to the 2018 benefit year. Therefore, all issuers of risk adjustment covered plans would be required to conduct an initial validation audit for the 2017 benefit year risk adjustment data validation, other than issuers with 500 billable member months or fewer Statewide as discussed above. Beginning with the 2018 benefit year risk adjustment data validation, issuers below the $15 million premium materiality threshold would not be required to conduct an initial validation audit every year. Under this proposal, HHS would still conduct random and targeted sampling under which issuers below the materiality threshold would be subject to an initial validation audit approximately every 3 years, beginning with 2018 benefit year risk adjustment data validation.[25] In addition, we explained that if the proposed approach for error rate payment adjustments outlined in the proposed rule were to be finalized, issuers below the $15 million threshold that are not selected for the random and targeted sampling might not have their risk adjustment transfers adjusted for a given benefit year.

We are finalizing the postponement of the materiality threshold to 2018 benefit year risk adjustment data validation, as proposed.

Comment: One commenter agreed with the proposal. Another commenter advocated for having a lower materiality threshold such as 12,000 or fewer billable member months. Some commenters stated that there should be no materiality threshold, and that all issuers should be subject to risk adjustment data validation.

[24] ''HHS-Operated Risk Adjustment Data Validation (HHS–RADV)—2016 Benefit Year Implementation and Enforcement.'' May 3, 2017. Available at *https://www.regtap.info/uploads/library/HRADV_PilotGuidance_5CR_050317.pdf.*

[25] In the 2018 Payment Notice, we stated that we would consider risk-based metrics such as an issuer's prior year risk adjustment data validation results and material changes to data submission, as measured by our quality metrics, in selecting issuers below the materiality threshold for more frequent initial validation audits.

Response: Although we appreciate the comments, we did not propose and are not modifying the level at which the materiality threshold is set in this rule. The proposal addresses the timing for implementation of the threshold and the applicability of potential adjustments to risk adjustment transfers for issuers at or below the $15 million threshold. All issuers of risk adjustment covered plans will be required to conduct an initial validation audit for the 2017 benefit year risk adjustment data validation, other than issuers with 500 billable member months or fewer Statewide as discussed above. Beginning with the 2018 benefit year, issuers at or below the $15 million premium threshold will not be required to conduct an initial validation audit every year. HHS will still conduct random and targeted sampling under which issuers below the materiality threshold would be subject to an initial validation audit approximately every 3 years, beginning with 2018 benefit year risk adjustment data validation. Under the policy finalized in this rule with respect to error rate payment adjustments, issuers below the $15 million materiality threshold that are not selected for the random and targeted sampling will not have their risk adjustment transfers adjusted.

v. Data Validation Sampling Methodology

Section 153.350(a) requires that a statistically valid sample of enrollees from each issuer of risk adjustment covered plans be validated. In the 2015 Payment Notice, HHS finalized its methodology for selecting the sample of enrollees for the initial validation audit for each issuer of a risk adjustment covered plan. We established a sample size per issuer for each State in which the issuer offers risk adjustment covered plans.[26] In the proposed rule, we explained that HHS would not calculate a risk score, or apply risk adjustment payment transfers except for high-cost risk pool transfers beginning with the 2018 benefit year, on behalf of a State in a market and risk pool when there is only one issuer in the market and risk pool. In addition, we proposed that the issuer would not be required to validate data for its plans in a risk pool that was not risk adjusted against another issuer in the State risk pool in the applicable benefit year. Therefore, we proposed to change the sampling methodology so that, beginning with the 2017 benefit year data validation, the initial data validation audit sample would only include enrollees from State risk pools in which there was more than one issuer.[27] We are finalizing this policy as proposed.

Comment: One commenter stated that the proposed approach to allow sole issuers to participate in another market in the State where it is not the sole issuer has the potential to create market instability, as non-similar plans are brought into the calculation.

Response: We clarify that, under the finalized policy, HHS would only sample from the issuer's risk pool where it is not the only issuer in the risk pool for the initial validation audit. Currently, the initial validation audit sample pulls from an issuer's population across a State, irrespective of risk pool. The finalized policy ensures that only enrollee data for which risk adjustment transfers were calculated in a risk pool are validated.

Comment: One commenter disagreed with our proposal due to concerns about accountability of sole issuers.

Response: For issuers that are the sole issuer in a risk pool, there is no risk adjustment transfer and thus, there is no payment or accountability to other issuers in that risk pool. As explained above, HHS will not calculate a risk score or risk adjustment payment transfers, on behalf of a State in a market and risk pool in which there is only one issuer, except for high-cost risk pool transfers beginning with the 2018 benefit year, and data submitted for high-cost risk pool transfers by all issuers will be subject to a separate audit. Therefore, we are finalizing the proposal to change the sampling methodology so that, beginning with 2017 benefit year risk adjustment data validation, the initial validation audit sample will only include enrollees from State risk pools in which there was more than one issuer and where HHS conducted risk adjustment on behalf of the State for the benefit year being validated.

vi. Mental and Behavioral Health Records

Under § 153.630(b)(6), the issuer of a risk adjustment covered plan must provide the initial validation auditor and second validation auditor with all relevant source enrollment documentation, all claims and encounter data, and medical record documentation from providers of services to each enrollee in the applicable sample without unreasonable delay and in a manner that reasonably assures confidentiality and security in transmission. Issuers have advised HHS that certain States' medical privacy laws may limit providers' ability to furnish mental and behavioral health records for risk adjustment data validation purposes. As we explained in the proposed rule, we believe that section 1343 of the PPACA and associated regulations require issuers of risk adjustment covered plans to furnish any records needed for purposes of the risk adjustment program, including mental and behavioral health records, and that the HIPAA Privacy Rule at 45 CFR 164.512(a) generally permits disclosures of protected health information that are required by law within the meaning of § 164.103. Nevertheless, we recognize that some State and Federal privacy laws impose requirements for mental and behavioral health information that are different from, and potentially more restrictive than, the HIPAA regulations. However, without the necessary mental and behavioral health information, the diagnosis code for an applicable enrollee cannot be validated and, therefore, it would be rejected during risk adjustment data validation.

To address these potential issues, we proposed to amend § 153.630(b)(6) to provide that, if a provider is prohibited from furnishing a full mental or behavioral health record by State or Federal privacy laws, the provider instead may furnish a mental or behavioral health assessment that providers routinely prepare, for validation of a mental or behavioral health diagnosis. We explained that, although HHS needs the full content of the mental or behavioral health record to ensure full validation of the accuracy of diagnosis codes, we believed that we can still perform some risk adjustment data validation based on the information contained in mental or behavioral health assessments in those instances in which State or Federal law prohibits submission of the full record. For risk adjustment data validation purposes, we would expect a mental or behavioral health assessment to be signed by a qualified provider who is licensed by the State to diagnose mental illness and, to the extent permissible under governing privacy and confidentiality laws, to contain: (i) The enrollee's name; (ii) sex;[28] (iii) date of birth; (iv) current

[26] The proposed rule described the sampling methodology incorrectly by stating that the sample would include 200 enrollees per issuer for each risk pool in which the issuer participates, instead of 200 enrollees per issuer across risk pools.

[27] For the 2018 and future benefit years, HHS would not require the sole issuer in the State market risk pool to include high-cost risk pool enrollees in its sample for data validation, as these payments will be subject to a separate audit process.

[28] For purposes of consistency, we made a technical revision to the name of this data element to ''sex'' in the final rule, rather than ''gender'' as

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status of all mental or behavioral health diagnoses; and (v) dates of service. We noted that ''psychotherapy notes,'' a subset of mental and behavioral health information that receives special protections under the HIPAA Privacy Rule, are not required for the purposes of risk adjustment data validation.[29] We also noted that some State and Federal privacy laws require that providers obtain patient consent before disclosing mental or behavioral health records, and that these consent requirements may apply to mental or behavioral health assessments. We clarified that we do not view a State or Federal law requiring patient consent as inconsistent with the risk adjustment data validation requirements to furnish a mental or behavioral health record or assessment. Additionally, we noted that certain substance use disorder patient records are subject to the Federal confidentiality law at 42 U.S.C. 290dd–2 and the regulations issued thereunder in 42 CFR part 2 and certain State laws, and generally require consent prior to disclosure. We stated that we believed that this proposal is consistent with the foregoing Federal and State confidentiality rules, and that the substance use disorder confidentiality requirements should govern when applicable. Therefore, issuers or providers may be required to obtain written patient consent to comply with this proposal.

We noted the proposal would allow issuers an additional avenue to achieve compliance by permitting abbreviated mental or behavioral health assessments for risk adjustment data validation in the event that a provider is subject to State or Federal privacy laws that prohibit the provider from providing a complete mental or behavioral health record to HHS. Under the proposal, to submit a mental or behavioral health assessment instead of the full mental or behavioral health record, a provider would be required to attest that relevant State or Federal privacy laws prohibit him or her from providing the complete mental or behavioral health record. We explained in the proposed rule that we also believed that the proposal supports the integrity of the risk adjustment data validation program by ensuring that an initial validation auditor obtains data that will enable proper validation of mental or behavioral health HCCs, which are susceptible to discretionary coding. Furthermore, we noted our belief that the flexibility to use mental or behavioral health assessments would minimize the burden on providers of complying with this requirement because providers may be able to utilize records they routinely prepare and may already have, as opposed to preparing special summaries solely for the purpose of risk adjustment data validation.

Based on our review of the comments we received, we are generally finalizing the amendments to § 153.630(b)(6) to permit providers that are prohibited by State law from furnishing a full mental or behavioral health record to submit an assessment instead. We are making one clarification to convey that this flexibility will not apply to providers that are prohibited solely by Federal law from furnishing a full mental or behavioral health record. We recognize that other State and Federal laws, including the Federal confidentiality law at 42 U.S.C. 290dd–2 and associated regulations that govern certain patient substance use disorder records potentially apply to mental or behavioral health assessments, and would require a provider to obtain enrollee consent before disclosing the assessment if applicable. We reiterate that the proposal on mental or behavioral health assessments was not intended to provide an exception to any applicable enrollee consent requirement under State or Federal law.

Comment: Most commenters supported the proposal. These commenters stated that the proposal would reduce burden, ensure compliance with privacy rules, and assist with the chart retrieval process. Others supported the proposal with certain modifications. For example, one commenter requested a safe harbor if mental health diagnosis failure, or error rates, are high due to noncompliance from mental health providers. Similarly, another commenter requested that HHS avoid punitive payment adjustments for issuers whose production of records is constrained by compliance with State law. The commenter also requested that HHS acknowledge the existence of varying State-specific limitations on consent for disclosure of mental or behavioral health records, evaluate the extent to which State-specific rules can be appropriately incorporated into the data collection, and engage in a separate solicitation of input from stakeholders on this topic.

Response: Since we only have final results from the first pilot year of risk adjustment data validation thus far, we do not currently have adequate experience to be able to determine whether failure rates for mental health diagnoses are higher than other diagnoses, and whether those failure rates are consistent by State. The policy for error rate payment adjustments finalized in this rule mitigates the potential for punitive payment adjustments, because only issuers with statistically meaningful failure rates will receive risk score error rates resulting in payment transfer adjustments.[30] We will continue to evaluate whether additional relief is necessary, based on analysis of risk adjustment data validation results. Our policy to permit the use of mental or behavioral health assessments by providers that are prohibited by State law from furnishing a full record is intended to offer broadly applicable relief and flexibility to account for the variation in privacy laws in particular States. Therefore, we do not intend to solicit input on or otherwise engage in an evaluation of State-specific requirements.

Comment: Two commenters expressed concern that initial validation auditors may interpret or utilize mental or behavioral health assessments differently, and requested that HHS provide guidance or training to ensure consistent interpretation of the assessments.

Response: We agree that consistent interpretation and utilization of mental and behavioral health assessments is important, and seek to encourage it. For purposes of risk adjustment data validation, the assessment is limited to the five discrete elements specified in § 153.630(b)(6), most of which are straightforward, so HHS does not anticipate a material risk of disparate interpretation or utilization of mental or behavioral health assessments by initial validation auditors. HHS continues to work to leverage existing provider networks and communication channels to educate providers on the HHS-operated risk adjustment data validation requirements.

Comment: One commenter requested the extension of flexibility to the actual submission of documentation regarding treatment for mental or behavioral health conditions, expressing concern that there may not be an affected

was specified in the proposed rule. HHS uses the data element of sex, as biologically determined, to calculate enrollees' risk scores under the PPACA risk adjustment program.

[29] ''Psychotherapy notes'' are notes recorded by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session, or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. Psychotherapy notes do not include medication prescription and monitoring, counseling session start and stop times, modalities and frequency of treatment, test results, and summaries of diagnoses, functional status, treatment plan, symptoms, prognosis, and progress to date. See § 164.501.

[30] Please see the above preamble section on ''Payment Adjustments for Error Rates'' for more information.

underlying record to identify in the first instance. The commenter also requested additional information regarding who bears responsibility for preparation of the mental or behavioral health assessment and how it differs from a full record.

Response: The provider is responsible for preparing the mental or behavioral health assessment, and the assessment is limited to the five elements specified in § 153.630(b)(6). When being used for risk adjustment data validation purposes, it should be accompanied by the provider's signature and an attestation that State privacy laws prohibit the provider from furnishing a complete medical record. This policy provides flexibility in cases where the State law prevents submission of the full record, but that flexibility does not extend to the provision of any documentation regarding mental or behavioral health conditions. HCCs without adequate documentation, whether through a full record or a mental or behavioral health assessment, would result in an error.

Comment: Several commenters did not support the proposal. For example, one commenter indicated that this policy of permitting mental or behavioral health assessments would not significantly reduce burden, and generally objected to the other State or Federal laws that may require the provider to obtain patient consent, indicating that doing so may not be possible. One commenter stated that requiring provider attestation or patient consent will add burden and reduce the likelihood of mental or behavioral health records being furnished by issuers in risk adjustment data validation. The commenter also expressed concern that there will likely be higher error rates for HCCs related to mental health or substance use disorders.

Response: HHS believes that the finalized policy to permit the use of existing mental or behavioral health assessments affords flexibility to providers to use an alternative source for the documentation that otherwise would be necessary under risk adjustment data validation to maintain the integrity of the risk adjustment program while complying with State and Federal privacy requirements. As discussed previously in this section and in the proposed rule, State and Federal privacy requirements may independently require a provider to obtain patient consent in order to furnish a mental or behavioral health assessment. In providing the flexibility to submit assessments for risk adjustment data validation purposes, HHS does not intend to limit or otherwise affect the application of any such consent requirements under State or Federal law, which provide important protections to enrollees.

HHS recognizes, however, that our policy to allow providers to furnish a mental or behavioral health assessment may impose a slight increase in the burden of compliance with risk adjustment data validation requirements because the assessment must be accompanied by an attestation from the provider. Attestations are necessary to demonstrate that the provider is prohibited from furnishing the complete medical record by State privacy laws, but we do not expect compliance with the attestation requirement to be difficult.

As noted above, HHS does not intend to exempt providers from any other applicable consent requirements under State or Federal law, and we do not yet have adequate experience as to whether failure rates will be higher for mental health conditions or substance use disorders. We reiterate that only issuers with statistically meaningful failure rates will receive risk score error rates and subsequent payment transfer adjustments pursuant to the policy finalized in this rule.[31] We will analyze risk adjustment data validation results to evaluate the impact of this policy on error rates, and will consider whether further refinements are appropriate.

Comment: Commenters expressed concern that enrollees could be waiving their HIPAA rights if their providers furnish medical records that include enrollees' diagnoses for risk adjustment data validation. The commenter suggested that if a diagnosis can be imputed by the presence of a prescription drug, HHS should include treatments for mental illness as a drug class in the risk adjustment models, to impute diagnoses for which a medical record cannot easily be obtained.

Response: As noted above and in the proposed rule, we believe that section 1343 of the PPACA and associated regulations require issuers of risk adjustment covered plans to furnish any records needed for purposes of the risk adjustment program, including mental and behavioral health records. The HIPAA Privacy Rule generally permits disclosures that are required by law (see 45 CFR 164.512(a)). We recognize that some State and Federal privacy laws impose requirements for mental and behavioral health information that are different from, and potentially more restrictive than, the HIPAA regulations, and may require that providers obtain patient consent before disclosing mental or behavioral health records or assessments. We do not view the risk adjustment data validation requirements to furnish a mental or behavioral health record or assessment as inconsistent with these consent requirements or involving any ''waiver'' of enrollee privacy rights.

As discussed in the 2018 Payment Notice, in specific instances, risk adjustment permits the use of prescription drugs to impute diagnoses. As noted elsewhere in this rule, HHS will continue to evaluate the inclusion of additional prescription drug classes in the risk adjustment model, including mental or behavioral health treatments, to potentially impute missing diagnoses for future benefit years.

Comment: One commenter requested that HHS provide issuers flexibility to develop standard language requiring the provider's signature to ease the administrative burden of creating mental or behavioral health assessments.

Response: The approach being finalized in this rule does not prevent an issuer from developing standard language for the provider attestation if the issuer believes it will help providers furnish mental or behavioral health assessments and other required documentation for risk adjustment data validation purposes.

Comment: Some commenters expressed concerns about the Federal rules governing confidentiality of substance use disorder patient records under 42 CFR part 2, or their alignment with the HIPAA Privacy Rule.

Response: The comments on the Federal rules governing confidentiality of substance use disorder patient records under 42 CFR part 2 and the HIPAA Privacy Rule concern regulations that are implemented and enforced by other agencies within HHS, the Substance Abuse and Mental Health Services Administration and the Office for Civil Rights, respectively. Although we appreciate these comments, we are not able to address them in this rulemaking.

vii. Inter-Rater Reliability Rates

Under § 153.630(b)(8), the initial validation auditor must measure and report to the issuer and HHS, in a manner and timeframe specified by HHS, its inter-rater reliability rates among its reviewers. An initial validation auditor must achieve a consistency measure of at least 95 percent for his or her review outcomes, except for the initial benefit years of risk

[31] Please see the above preamble section on ''Payment Adjustments for Error Rates'' for more information.

adjustment data validation, for which the initial validation auditor may meet an inter-rater reliability standard of 85 percent. Consistent with our decision to make the 2016 benefit year another pilot year as referenced above, we proposed to amend § 153.630(b)(8) to add the 2016 benefit year as an initial year of risk adjustment data validation for which the initial validation auditor may meet the lower inter-rater reliability standard of 85 percent. We are finalizing the amendment to § 153.630(b)(8) as proposed.

Comment: All commenters supported the addition of the 2016 benefit year as an initial year of risk adjustment data validation for which the initial validation auditor may meet an inter-rater reliability standard of 85 percent. One commenter noted that permitting the 85 percent standard for another year would allow issuers to gain an additional year of experience and process improvement before the standard is increased.

Response: We agree with commenters and are finalizing the amendment to § 153.630(b)(8) as proposed.

viii. Civil Money Penalties

An effective risk adjustment data validation program is essential to the proper functioning of the HHS-operated risk adjustment program. In order to enforce risk adjustment data validation standards when operating risk adjustment data validation on behalf of a State, we proposed to clarify and amend the bases upon which HHS may impose CMPs for violations of risk adjustment data validation requirements.

To give HHS additional flexibility for ensuring compliance with the risk adjustment data validation requirements and in light of our experience in the first pilot year of the risk adjustment data validation program, HHS proposed to amend § 153.630(b)(9) to give HHS the authority to impose a CMP on an issuer of a risk adjustment covered plan in the event of misconduct or substantial non-compliance with the risk adjustment data validation standards and requirements. Specifically, we proposed to amend § 153.630(b)(9) to state that, if an issuer of a risk adjustment covered plan (1) fails to engage an initial validation auditor; (2) fails to submit the results of an initial validation audit to HHS; (3) engages in misconduct or substantial non-compliance with the risk adjustment data validation standards and requirements applicable to issuers of risk adjustment covered plans; or (4) intentionally or recklessly misrepresents or falsifies information that it furnishes to HHS, HHS may impose CMPs in accordance with the procedures set forth in § 156.805(b) through (e). We note that § 153.630(b)(9) already addresses the possible imposition of CMPs for (1) and (2) above, and provides a cross-reference to § 156.805, which contains the bases and procedures for imposing CMPs for (3) and (4) above. Section 153.630(b)(9) provides the authority to assess CMPs on all issuers of risk adjustment covered plans, not just issuers on an FFE as does § 156.805.[32] We clarified that the proposal to impose CMPs for (3) and (4) would apply to all issuers of risk adjustment covered plans, not just those issuers on an FFE. We noted that the CMP authority would be in addition to HHS's ability to adjust an issuer's transfers under § 153.350(c).

As previously noted in the Second 2013 Program Integrity Rule, and in the 2015 Payment Notice, we proposed that HHS's possible application of CMPs would continue to take into account the totality of the issuer's circumstances, including such factors as an issuer's previous record of non-compliance (if any), the frequency and level of the violation, and any aggravating or mitigating circumstances. Additionally, we would continue to impose any CMPs so that the level of the enforcement action is proportional to the level of the violation. While we reserved the right to impose penalties up to the maximum amounts set forth in § 156.805(c), as a general principle, we explained that we intend to work collaboratively with issuers to address any problems in conducting the risk adjustment data validation process.

We believe this additional CMP authority will improve program integrity and fairness by permitting HHS the authority to assess CMPs on issuers that engage in misconduct in risk adjustment data validation. Although § 153.630(e) permits HHS to adjust payments and charges for issuers that do not comply with audit requirements and standards, this provision only makes the markets whole in the event of a violation of the risk adjustment data validation standards or misconduct. We do not believe this provision provides a sufficient deterrent effect to ensure program integrity of the risk adjustment data validation program. Additionally, we believe this additional authority is necessary in light of the policies finalized in the 2018 Payment Notice, specifically, the concerns HHS highlighted around gaming and the inclusion of prescription drug data in the risk adjustment model. We are finalizing as proposed the amendments to § 153.630(b)(9) to clarify and strengthen HHS's CMP authority. We also clarify that HHS would not impose a CMP under § 153.630(b)(9) for a benefit year on an issuer that is not required to submit an initial validation audit for risk adjustment data validation for that benefit year.

Comment: Most of the comments received supported the proposal. One commenter requested definitions for misconduct, substantial noncompliance, and reckless misrepresentation, along with examples for each case under which an issuer could receive a CMP.

Response: The terms misconduct, substantial noncompliance, and reckless misrepresentation are incorporated from § 156.805(a)(1) and (5). Examples of issuer misconduct that could warrant imposition of a CMP under the amended § 153.630(b)(9) include knowingly hiring an initial validation auditor who has conflicts of interest, or failing to ensure confidentiality and security of data transmitted to the initial validation auditor or second validation auditors. Examples of substantial noncompliance include unreasonable delays in providing complete enrollment documentation, claims and encounter data, or medical records documentation to an auditor, or failing to properly oversee an initial validation auditor. However, the determination of whether conduct rises to the level of any of these terms in any specific case is highly fact sensitive, involving consideration of any mitigating or aggravating factors.

ix. Adjustment of Risk Adjustment Transfers Due to Submission of Incorrect Data

On September 2, 2015, HHS released the *Adjustment of Risk Adjustment Transfers Due to Submission of Incorrect Data* guidance,[33] describing the process by which HHS addresses instances of materially incorrect EDGE server data submissions. We reiterated this guidance on November 3, 2017, through the release of *Evaluation of EDGE Data Submissions for the 2017 Benefit Year.*[34] We proposed to include risk adjustment data validation as a

[32] Pursuant to § 153.20, *risk adjustment covered plan* means, for the purpose of the risk adjustment program, any health insurance coverage offered in the individual or small group market with the exception of grandfathered health plans, group health insurance coverage described in 45 CFR 146.145(c), individual health insurance coverage described in 45 CFR 148.220, and any plan determined not to be a risk adjustment covered plan in the applicable Federally certified risk adjustment methodology.

[33] Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RA-Adjustment-Guidance-9-2-15.pdf.*

[34] Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-Submissions-2017.pdf.*

method of discovering materially incorrect EDGE server data submissions and making adjustments pursuant to § 153.630(e), as described in the September 2, 2015 guidance.[35] We proposed that demographic or enrollment errors discovered during risk adjustment data validation would be the basis for an adjustment to the applicable benefit year transfer amount, rather than the subsequent benefit year risk score. The elements being validated are related to the transfer formula and demographic variables in the risk adjustment models. We explained that we believe the process of identifying demographic and enrollment errors is substantially similar to a discrepancy in the transfer formula, which is addressed in the current benefit year as part of the EDGE data discrepancy process under § 153.710, as opposed to a discrepancy in underlying enrollee diagnoses contributing to risk scores, which is addressed through subsequent year risk score adjustments as part of risk adjustment data validation.

An overstatement or understatement of premium data may affect issuers differently, because it will lead to an increase or decrease in the absolute value of the magnitude of the risk adjustment transfers (and will affect the calculation of the geographic rating area factors). Therefore, an issuer's submission of incorrect EDGE server premium data may have the effect of increasing or decreasing the magnitude of risk adjustment transfers to other issuers in the market, depending on the direction of the premium error, holding constant the other elements of the payment transfer formula. In cases where there is a material impact on risk adjustment transfers for that particular market as a result of incorrect EDGE server premium data, HHS would calculate the dollar value of differences in risk adjustment transfers, and, where the difference is detrimental to one or more issuers in the market, adjust the other issuers' risk adjustment transfer amount by that calculation, and increase the risk adjustment charge (or decrease the risk adjustment payment) to the issuer that made the data error, in order to balance the market.[36] We explained that we believe this approach would allow HHS to operate the risk adjustment program efficiently, while ensuring that issuers do not profit from their data submission errors or harm their competitors in the relevant market. We sought comment on this proposal.

We are finalizing this policy as proposed.

Comment: Commenters supported the proposal, or agreed with it but requested additional clarification. For example, one commenter requested examples of materially incorrect data submissions. Another commenter sought clarification on certain technical issues related to the proposal, including the definition of demographic and enrollment data errors, whether these errors will impact elements of the transfer formula, the error rate, or both, and the timing of any adjustments that HHS would make with respect to current year risk adjustment transfer amounts and related data transfer element errors. One commenter supported HHS's current approach of taking a subsample of 50 enrollees to verify demographic and enrollment information, but stressed that the subsample results should not be the sole basis for applying current year transfer adjustments. Rather, if errors are identified from the subsample, HHS should then investigate the issuer's data further to assess if there were materially incorrect EDGE data submissions.

Response: We clarify that significant errors found in the risk adjustment data validation demographic and enrollment subsample review will result in communications from HHS to the issuer regarding the issuer's underlying data before the potential application of any adjustments to risk adjustment transfers. The demographic and enrollment data elements collected for purposes of risk adjustment are date of birth, sex, plan identifier, enrollment start and end dates, premium amount, and rating area. In addition to the issues described above regarding incorrect premium, certain demographic or enrollment errors could indicate the presence of larger issues such as assignment of enrollees to the incorrect model or metal level, which would lead to incorrect risk scores and a miscalculation of the AVs and induced demand factors (IDF) in the transfer formula, or incorrect age factors. If this occurs, we would initiate a separate process outside of risk adjustment data validation to further evaluate the impact of the incorrect data submission, determine whether the market needs to be made whole due to the errors, and then make the necessary adjustments to affected issuers. Therefore, HHS will not be relying solely on subsample results as the basis for applying current year transfer adjustments. Whether an error has an effect on the transfer formula, error rate, or both amounts will depend on the specifics of the error. For example, if an error affects premiums alone, only the Statewide average premium would need to be adjusted. HHS intends to be in communication with affected issuers throughout the second validation audit process, and to resolve potential discrepancies in a manner similar to the EDGE data submission discrepancy process.

h. Risk Adjustment User Fee for the 2019 Benefit Year (§ 153.610(f))

As noted above, if a State is not approved to operate, or chooses to forgo operating its own risk adjustment program, HHS will operate risk adjustment on its behalf. In 2019, HHS will be operating a risk adjustment program in every State. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of States is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the per member per month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A–25R established Federal policy regarding user fees, and specified that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. The risk adjustment program will provide special benefits as defined in section 6(a)(1)(B) of Circular No. A–25R to issuers of risk adjustment covered plans because it mitigates the financial instability associated with potential adverse risk selection. The risk adjustment program also contributes to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual and small group markets.

In the 2018 Payment Notice, we calculated the Federal administrative expenses of operating the risk adjustment program for the 2018 benefit year to result in a risk adjustment user fee rate of $1.68 per billable member per year or $0.14 PMPM, based on our estimated contract costs for risk adjustment operations and estimates of billable member months for individuals enrolled in a risk adjustment covered plan. For the 2019 benefit year, we proposed to use the same methodology to estimate our administrative expenses to operate the program. These contract costs cover development of the model

[35] This guidance is also included in the *Evaluation of EDGE Data Submissions for the 2017 Benefit Year,* released on November 3, 2017, available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-Submissions-2017.pdf.*

[36] Calculation of the dollar value will include adjustment to the Statewide premium average and, to the extent possible, adjustment to the geographic cost factor.

and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, and operational support. To calculate the user fee, we divided HHS's projected total costs for administering the risk adjustment programs on behalf of States by the expected number of billable member months in risk adjustment covered plans in HHS-operated risk adjustment States for the benefit year.

We previously estimated that the total cost for HHS to operate the risk adjustment program on behalf of States for 2019 will be approximately $38 million, and the risk adjustment user fee would be $1.68 per billable member per year, or $0.14 PMPM. However, we now estimate the cost for HHS to operate the risk adjustment program on behalf of States for the 2019 benefit year to be approximately $40 million, and are finalizing a risk adjustment user fee of $1.80 per billable member per year, or $0.15 PMPM, to take account of eligible administrative and personnel costs related to the operation of the HHS-operated risk adjustment program that were previously excluded from the estimate.

C. Part 154—Health Insurance Issuer Rate Increases: Disclosure and Review Requirements

1. Applicability (§ 154.103)

Since July 18, 2011, issuers have been required to submit rate filing justifications for rate increases for non-grandfathered plans in the individual and small group markets. This requirement was established, in part, to carry out the Secretary's responsibility, in conjunction with States, under section 2794(b)(2)(A) of the PHS Act to monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange. Student health insurance coverage is considered by HHS to be a type of individual market coverage and is generally subject to the PHS Act individual market requirements, which has included rate review. We proposed to modify § 154.103(b) to exempt student health insurance coverage from the Federal rate review requirements, effective for plan or policy years beginning on or after January 1, 2019. As we discussed in the proposed rule, and as commenters noted, student health insurance coverage is generally rated and administered differently from other forms of individual health insurance coverage.[37]

States have allowed rating practices for student health insurance coverage to be more in line with large group pricing, in which experience rating and other factors can be used to determine rates. Because student health insurance coverage is typically experience rated, and is typically only available to students and their dependents with an open enrollment period coinciding with the start of the academic year, it is exempt from single risk pool rating requirements and not guaranteed to be available or renewable to individuals who are not students or dependents of students in an institution of higher education. We are finalizing the exemption as proposed, except that we are modifying the applicability date to align with the timing of when student health insurance coverage typically begins, such that the exemption will be effective for student health rate filings for the next plan year. This change, effective for student health insurance coverage effective on or after July 1, 2018, will reduce the regulatory burden on States and issuers of student health insurance plans.

Comment: Most commenters supported the proposal to exempt student health insurance coverage from Federal rate review requirements. Commenters suggested that the exemption should apply to coverage effective on or after July 1, 2018, to coincide with the traditional school year. Some commenters expressed concern that exempting student health insurance coverage would result in minimal oversight and decreased affordability.

Response: We are finalizing the exemption and it will apply to student health insurance coverage, as defined in § 147.145, with an effective date on or after July 1, 2018. We note that States maintain the flexibility to review rate increases of any size and any other aspects of student health insurance coverage. In States that do not have an Effective Rate Review Program, we will continue to monitor the compliance of student health insurance coverage with applicable market rating reforms based on complaints and as part of targeted market conduct examinations. In States where we are enforcing market reforms, we will continue to review form filings for student health insurance coverage for compliance with applicable PHS Act individual market requirements.

[37] *See* preamble discussion in the final rule, ''Health Insurance Market Rules; Rate Review'' 78 FR 13406, 13424 (February 27, 2013).

2. Rate Increases Subject to Review (§ 154.200)

Section 2794(a)(1) of the PHS Act requires the Secretary, in conjunction with States, to establish a process for the annual review of unreasonable premium increases for health insurance coverage. Section 2794(a)(2) of the PHS Act requires health insurance issuers to submit to the Secretary and relevant State a justification for an unreasonable premium increase prior to implementation. States may establish a more robust review process, and many have.

Section 154.200(a)(1) currently provides that a rate increase for single risk pool coverage beginning on or after January 1, 2017 is subject to a reasonableness review if: (1) The average increase, including premium rating factors described in § 147.102, for all enrollees, weighted by premium volume for any plan within the product, meets or exceeds 10 percent; or (2) the increase exceeds a State-specific threshold approved by the Secretary. We proposed to amend this provision to establish a 15 percent default threshold for reasonableness review, in recognition of significant rate increases in the past number of years, rather than the current 10 percent default threshold.[38]

Section 154.200(a)(2) currently requires States to submit a proposal to the Secretary for approval of any State-specific threshold. We proposed to amend § 154.200(a)(2) to require submission of a proposal only if the State-specific threshold is higher than the Federal default threshold. We proposed this change to reduce burden and promote State flexibility.

We also proposed to delete paragraph (b) in its entirety. That paragraph currently requires that the Secretary publish a notice each year indicating which threshold applies to each State. For States that request a State-specific threshold above what is set by CMS, CMS noted it would continue to post information on its website beginning with requests submitted on or after January 1, 2019.

We proposed to redesignate paragraph (c) as paragraph (b) and revise that paragraph to delete the language related

[38] The 10 percent threshold was established in the ''Rate Increase Disclosure and Review'' Final rule (76 FR 29963, May 23, 2011) based upon three indices. These indices are: (1) The medical component of the Consumer Price Index (CPI); (2) the National Health Expenditure data (NHE); and (3) the Standard and Poor's Healthcare Economic Commercial Index. The threshold was finalized at 10 percent based on the analysis of the trend in health care costs and rate increases provided in the preamble to the proposed rule.

to rates filed for coverage beginning before January 1, 2017, currently captured in paragraph (c)(1) as this provision is no longer necessary.[39] We proposed to redesignate paragraph (d) as paragraph (c). Finally, we proposed conforming changes to update the cross references in § 154.200 to align with the changes described above.

We are finalizing these changes as proposed with one modification, described below. These changes will apply to single risk pool rate filings submitted by issuers for plan or policy years beginning on or after January 1, 2019.

Comment: Some commenters supported a threshold increase, noting that raising the threshold to 15 percent would allow regulators to focus their attention on higher rate increases and reduce the regulatory burden for both States and issuers. Other commenters supported raising the threshold, but did not specify an alternative to 10 percent. Many commenters opposed changing the reasonableness review threshold to 15 percent, concerned that the change may normalize excessive increases. Other commenters opposed the change because it would negatively affect transparency of rate setting, noting that the Consumer Justification Narrative (Part II of the Rate Filing Justification) is only required for increases that meet or exceed the review threshold. Some commenters suggested a 6 percent threshold would be appropriate because that would be in line with health expenditures and still above the general rate of inflation. A few commenters suggested there should be a 15 percent threshold at the product level and 20 percent threshold at the plan level.

Response: We note that the threshold set by HHS constitutes a minimum standard. By increasing the threshold trigger to 15 percent, we are providing an opportunity for States to reduce their review burden, although most States currently employ stricter rate review standards and may continue to do so. Additionally, increasing the Federal default threshold for review will reduce burden for issuers. After an analysis of all rates subject to review that were determined to be ''unreasonable'' since the inception of the review threshold, only one filing with this determination has fallen between the 10 to 15 percent range. For these reasons, we do not believe this change will normalize excessive increases.

We are not lowering the threshold to 6 percent, as doing so may increase the burden on issuers and States. We are not establishing two thresholds (one at the product level and one at the plan level). When determining whether an increase is subject to review, rate increases are calculated at the plan level. That ensures that a plan that experiences a significant rate increase does not avoid review simply because the average increase for the product did not meet or exceed the applicable threshold. Because consumers are affected by rate increases at the plan level, we believe that increases for the plan, not the product, should continue to be the trigger for determining whether an increase is subject to review.

We expect the change to have a minimal impact on transparency. All issuers must continue to submit a Uniform Rate Review Template (URRT) (Part I of the Rate Filing Justification) for all single risk pool plan submissions. Issuers offering a QHP or any single risk pool submission containing a rate increase of any size must continue to submit an actuarial memorandum (Part III of the Rate Filing Justification). We are finalizing the proposal to change the Federal default review threshold to 15 percent beginning with single risk pool rate filings submitted by issuers for plan or policy years beginning on or after January 1, 2019.

Comment: Some commenters opposed CMS requiring submission of a proposal (and posting of that proposal) only if the State-specific threshold is higher than the Federal default threshold.

Response: The Federal review threshold is a minimum standard. States are able to apply a stricter standard, and many already do. Because States that apply a lower threshold meet the Federal minimum standard, we do not believe it is necessary or appropriate to require those States to submit a proposal to CMS. Therefore, we are finalizing the proposed changes to § 154.200(a)(2) with the following modification: We added language to clarify that these State proposals must be submitted in the form and manner specified by the Secretary. CMS will only require a proposal from States requesting a higher threshold. States that impose stricter standards will communicate those standards to their issuers as they currently do with many other aspects of State-specific requirements. CMS will post information from States that request a threshold higher than 15 percent and will issue further guidance on the process for submission and review of such State requests.

3. Submission of Rate Filing Justification (§ 154.215)

Section 154.215(h)(2) includes a reference to 45 CFR 5.65, which defined trade secret and confidential commercial or financial information under HHS regulations implementing the Freedom of Information Act, 5 U.S.C. 552. HHS revised 45 CFR part 5 in a final rule issued on October 28, 2016, effective on November 28, 2016 (81 FR 74930). We proposed to make a technical correction to § 154.215(h)(2) to refer to 45 CFR 5.31(d) because 45 CFR 5.65 no longer exists and § 5.31(d) now lists the reasons a record may be withheld. We are finalizing the change as proposed.

Comment: Some commenters opposed CMS's use of the Freedom of Information Act and requested issuer information be provided without any redaction.

Response: We proposed and are finalizing a technical correction to the regulatory reference. We did not propose any change to our interpretation of a trade secret and confidential commercial or financial information. The issuer may submit a redacted actuarial memorandum, but CMS does not make any redaction beyond what is submitted in the rate filing.

4. Timing of Providing the Rate Filing Justification (§ 154.220)

Section 154.220(b) provides that a health insurance issuer must submit applicable sections of the Rate Filing Justification for all single risk pool coverage in the individual or small group market by the earlier of (1) the date by which the State requires submission of a rate filing; or (2) the date specified in guidance by the Secretary. We have interpreted that section to require submission of all rate filings, for both QHPs and non-QHPs, at a uniform time.[40] We proposed to allow a State to set a later submission deadline for issuers who offer non-QHPs only, starting with the 2019 plan year. We are finalizing the change as proposed.

Comment: Some commenters expressed concern that the proposal provides an advantage to issuers offering only non-QHPs and may provide an opportunity for competitors to shadow price. Many commenters supported the proposal, in order to reduce State burden.

Response: We are finalizing the proposal. We remind issuers that offer both QHPs and non-QHPs in a market in a given State to submit its rate filing

[39] This standard (that is, the average increase for all enrollees weighted by premium volume meets or exceeds the applicable threshold), however, continues to apply to rates filed for coverage beginning before January 1, 2017, including with respect to compliance reviews and enforcement actions.

[40] 80 FR 10782.

in accordance with the deadlines established for QHPs to support regulatory review of compliance with the single risk pool requirement. Establishing a later submission deadline for issuers that offer only non-QHPs is a State option, not a requirement. We believe it will reduce burden while empowering States to pick the timeframe that works best for their markets, and also accounts for market differences between States. We also remind States and issuers that even if the submission deadlines differ; all information must be submitted to CMS by the earlier of the State deadline or the Federal deadline. We also remind States and issuers that only submission deadlines may vary; uniform posting will still be required, as discussed below, to help mitigate the potential for shadow pricing and other anti-competitive behaviors.

5. Determinations of Effective Rate Review Programs (§ 154.301)

a. State Posting of Rate Increases

We proposed to modify § 154.301(b)(2), by reducing the advance notification required, so that a State with an Effective Rate Review Program must notify us in writing, no later than 5 business days prior to the date it intends to make any proposed or final rate filing information public if the State will be posting prior to the date specified by the Secretary. We are finalizing this change as proposed.

Comment: The majority of commenters supported this proposal. Some commenters requested that CMS require States to inform issuers prior to posting. Some commenters requested that CMS require States to post rate filing information on State websites even if the information is also posted on CMS's website. Two commenters opposed the proposal because they interpreted the proposal as a reduction to the public's opportunity to review and comment.

Response: We appreciate the importance of State communication with issuers, and we expect States to maintain satisfactory communication regarding posting deadlines to issuers, but decline to propose requirements related to such. We also did not propose and are not making changes to the requirements regarding States posting on their own website. States are permitted to use CMS's website because we are mindful of the burden and cost associated with such posting, but we encourage States to consider posting rate filing information directly on their respective websites, while also providing a link to the CMS website. We are finalizing the proposal. This change will reduce the amount of time prior to posting that the State must notify CMS, but does not reduce the public comment period.

b. Posting of Rate Increases

Section 154.301(b)(3) provides that a State with an Effective Rate Review Program must ensure that information regarding rate increases is made available to the public at a uniform time for all proposed and final rate increases, as applicable, in the relevant market segment and without regard to whether coverage is offered on or off of an Exchange. That provision was codified in order to set a level playing field, to prevent issuers that submit rate filings later from having an advantage over their competitors that submitted rate filings earlier.

We proposed to eliminate the requirement for uniform posting so that States that have an Effective Rate Review Program would have the option to post proposed and final rate filing information on a rolling basis. We are not finalizing this proposal.

Comment: A few commenters supported the proposal, but the majority of commenters opposed the proposal, noting that uniform posting protects issuers from shadow pricing and ensures a level playing field in a fair competitive market. Those commenters were also concerned that posting on a rolling basis may promote manipulation by some market competitors, and could inadvertently contribute to market destabilization.

Response: We proposed to give States the option to post rate increase information on a rolling basis in order to accommodate a few States that have laws requiring immediate posting upon receipt. We did not receive overwhelming support for that change, as only two States supported it; the majority of commenters opposed the change. We agree with commenters' concerns that removing the requirement for uniform posting could have unintended, negative effects on competition in the markets. Some commenters also feared that posting on a rolling basis could cause confusion among consumers, and eliminate the likelihood of consumers easily comparing a rate increase across all products. We do not want to provide unfair advantages to issuers that file later in the filing season, or contribute to consumer confusion. Therefore, we are not finalizing the proposal. We are retaining § 154.301(b)(3) as it exists in our current regulations to require that a State with an Effective Rate Review Program ensure that the information in § 154.301(b)(1)(i) and (ii) is made available to the public at a uniform time for all proposed and final rate increases, as applicable, in the relevant market segment and without regard to whether coverage is offered on or off of an Exchange.

D. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Standardized Options (§ 155.20)

In the 2017 Payment Notice, HHS introduced standardized options (also now referred to as Simple Choice plans). A standardized option is a QHP offered for sale through an individual market Exchange that either has a standardized cost-sharing structure specified by HHS in rulemaking or has a standardized cost-sharing structure specified by HHS in rulemaking that is modified only to the extent necessary to align with the high deductible health plan (HDHP) requirements under section 223 of the Code or the applicable annual limitation on cost sharing and HHS actuarial value requirements. For the 2017 and 2018 benefit years, HHS specified standardized options in rulemaking, encouraged issuers to offer such plans, and provided differential display of these plans on *HealthCare.gov*.

As noted in the proposed rule, we seek to encourage free market principles in the individual market, and to maximize innovation by issuers in designing and offering a wide range of plans to consumers. We noted concerns that providing differential display for these plans may limit enrollment in coverage with plan designs that do not match the standardized options, removing incentives for issuers to offer coverage with innovative plan designs. We believe that encouraging innovation is especially important now, given the stresses faced by the individual market. Therefore, we are finalizing our proposal to not specify any standardized options for the 2019 benefit year, and not to provide differential display for standardized options on *HealthCare.gov*. Agents, brokers, and issuers that assist consumers with QHP selection and enrollment as described in § 155.220(c)(3) and § 156.265(b), respectively, are also not required to provide differential display for standardized options on those third-party websites. We are finalizing the policies on standardized options as proposed.

Comment: Many commenters supported the proposed policy to discontinue standardized options for the 2019 plan year. Commenters noted that they believed standardized options

stifled issuers' ability to develop innovative plan designs. Commenters also noted that because of the differential display, issuers may have offered and consumers may have purchased HHS-designed plans that did not best meet consumers' needs. Other commenters noted that consumers may have mistakenly thought that standardized options were superior to other plans; and that other tools, such as AV, EHB, and other *HealthCare.gov* plan filters were sufficient in assisting consumers in selecting and comparing plans. Other commenters questioned the benefits of standardized options.

Many other commenters supported HHS continuing to specify standardized options, noting that they are a useful consumer-support tool that aids in plan comparisons and selection and that withdrawing the standardized options could create confusion for consumers, especially those with low health literacy or certain health conditions. Others noted that removing the standardized option designation could make plan selection more difficult resulting in fewer people enrolling in QHPs.

Some commenters noted that the standardized cost sharing encourages issuers to innovate on other plan features and encourages issuers to compete on networks and formularies. Other commenters noted that the standardized plan designs ensure offerings had certain desirable features, such as fewer specialty drug tiers and first dollar coverage. Commenters noted that standardized options were voluntary and therefore could not stifle innovation. Another commenter noted that removing standardized options could result in issuers designing plans specifically for a healthy population. Another commenter supported making standardized options mandatory and expanding to include SADPs.

Response: As we noted in the proposed rule, we believe that not specifying standardized options for the 2019 plan year will remove disincentives for issuers to offer coverage with innovative plan designs. We agree that issuers are in the best position to design and offer innovative plan designs. We are similarly finalizing the removal of the differential display of standardized options.

As we noted in the 2017 Payment Notice final rule,[41] we designed the standardized options to be as similar as possible to the most popular (weighted by enrollment) QHPs in the FFEs in order to minimize market disruption and impact on premiums. Consequently, we believe that the plan design features, such as annual limitations on cost sharing and deductibles, previously specified as part of standardized options are mostly available to consumers in FFEs. Therefore, we do not believe it is necessary to mandate or otherwise further provide an incentive for issuers to offer plans that meet the characteristics of standardized options.

We agree with commenters that *HealthCare.gov* plan filters for other tools are sufficient to enable most consumers to make plan selections. However, we continue to explore strategies to make shopping on *HealthCare.gov* as easy as possible, and to better support consumers in choosing coverage that is best for them. Consumers are able to select a QHP based on metal level, and are generally offered coverage of a similar set of essential health benefits. We agree with commenters that certain populations with specific health conditions may not purchase a QHP that best meets their needs if they merely select based on a standardized option designation. Standardized options offer simple plan comparisons at a high level to assess comparability on cost sharing of certain services. However, consumers with specific health conditions may be better served by a different QHP that provides benefits better suited for their individual needs. By removing standardized options, we are mitigating the risk that consumers with special coverage needs choose a standardized option plan that may not provide the optimal mix of cost-sharing protections, benefits, and networks for their situation. We believe these benefits outweigh any potential additional difficulty in selecting a QHP that could result from the elimination of the standardized option designation.

For these reasons we are finalizing the policy as proposed.

Comment: One commenter requested clarification that if the proposal is finalized as proposed standardized options would not appear on *HealthCare.gov* or be designated in public use files. Another commenter requested that HHS release data related to standardized options offerings and enrollment publicly prior to making a decision about ceasing to specify standardized options.

Response: The proposal is being finalized as proposed. Therefore standardized options will not display as ''Simple Choice Plans'' on *HealthCare.gov*, nor will information be collected and reported in public use files for the 2019 benefit year. We have previously released data regarding standardized options offerings in public use files. We believe releasing data regarding recent enrollment in standardized options could cause competitive harm to issuers, but intend to continue to release historical enrollment data for all QHPs, including standardized options, in the future.

Commenter: A commenter noted that standardized options assist States in Federal and State review, certification, and oversight.

Response: States have previously been able to complete QHP certification, review, and oversight for issuers that are not offering standardized options, and therefore, we believe that they will be able to continue doing so without relying on standardized options.

2. General Standards Related to the Establishment of an Exchange

a. Flexibility for State Exchanges and State Exchanges on the Federal Platform (§ 155.106 and § 155.200)

While the PPACA allowed each State to operate its own State Exchange, currently 11 States and the District of Columbia operate their own Exchanges, five States utilize the SBE–FP model, and FFEs operate in the remaining 34 States. We seek to support innovation by States operating State Exchanges by providing opportunities for increased program flexibilities to help support the retention and financial self-sustainability of States that adopted the SBE model. In particular, we sought comment on how HHS can best support State Exchange efforts to utilize commercial platform services, including what type of technical support would be useful and what, if any, specific regulatory changes would facilitate the use of these services.

We also proposed to explore strategies to make the SBE–FP model more appealing and viable to States with FFEs, as well as to support retention of existing SBE–FPs. As codified in the 2017 Payment Notice, the SBE–FP model allows States to establish the legal status of their Exchanges as State Exchanges while leveraging the economies of scale available through the Federal eligibility and enrollment platform and information technology infrastructure. The SBE–FP model offers States opportunities to retain more control over their Exchanges than if an FFE operated in the State, as it allows them to control plan management and consumer assistance activities, without the additional responsibility of building the infrastructure required to operate an information technology eligibility and enrollment platform. Accordingly, we seek to explore options for streamlining current requirements and leveraging private sector and Federal platform

[41] 81 FR at 12289 (March 8, 2016).

technologies and advances to increase opportunities for those States interested in remaining or becoming SBE–FPs. We also intend to continue to explore areas where current authority, technology, and operational capacities would permit HHS to provide additional options in operational functions to SBE–FPs and provide SBE–FPs with a greater role in decision-making. We sought comment on ways to strengthen and enhance the SBE–FP model.

Comment: Several commenters supported further actions by HHS to allow SBE–FPs greater access to enrollment data and consumer assistance tools, and supported efforts to customize the Federal platform to meet SBE–FP needs. Other commenters encouraged HHS to lower or eliminate the SBE–FP user fee, increase predictability of the user fee, or to tailor the user fee to an Exchange based on use of certain Federal platform options. One commenter proposed HHS consider new Federal grant funding for State Exchanges to purchase commercial technology platforms, while others requested HHS reduce market uncertainty and further streamline eligibility verification requirements to support the success of SBEs. Another commenter requested that HHS promote regional State Exchanges to mitigate financial sustainability challenges faced by smaller States. Several commenters encouraged the use of direct enrollment and enhanced direct enrollment capabilities and private and Federal platform technologies by State Exchanges and SBE–FPs. One commenter suggested State Exchanges consolidate into a single entity utilizing Federal platform technology while enabling private partnerships and non-profit entities to perform consumer facing functions. Two commenters suggested the Federal platform include functionality to support independent enrollment in dental plans in SBE–FPs.

Other commenters supported the concepts of innovation and increased customization of the Federal platform, but suggested HHS prioritize improvements to the overall *HealthCare.gov* system infrastructure before focusing on State-specific enhancements to *HealthCare.gov*. Some commenters emphasized the need for guardrails to protect patients and consumers as HHS explores flexibilities and innovations in Exchange models. One commenter expressed concern that HHS's support for expanding the SBE–FP model signaled an intent to reduce Federal support for small population States and requested assurance the FFE would continue to be available for small States.

Response: We appreciate the comments, and will consider them as we continue to explore incentives and program flexibilities for the SBE and SBE–FP models. The SBE–FP model was intended to improve States' ability to operate efficient Exchanges by providing the option for State Exchanges to agree to rely on the Federal eligibility and enrollment platform and information technology infrastructure to carry out certain functions in order for the State to fulfill requirements as a State Exchange. We continue to explore ways to make this a more appealing option to States that currently have FFEs. In 2017, at the request of the SBE–FPs, we shared new data with the SBE–FPs to enhance their consumer outreach functions, customer relationships, and fiscal planning activities. HHS intends to continue to enhance these data-sharing efforts with SBE–FPs to support their ability to fulfill their responsibilities. However, at this time, HHS is unable to offer a menu of Federal platform functionalities to an SBE–FP. Likewise, at this time, HHS is unable to offer State-specific customization of the Federal platform agreement, but will continue engaging with SBE–FPs to refine the agreement. We also note that § 155.140 permits States to participate in regional Exchanges spanning two or more States. This allows States interested in operating State Exchanges to partner with each other and leverage economies of scale by sharing a common information technology infrastructure or platform, and HHS encourages States to explore this as an option. States that are interested in this option would need to obtain HHS approval to operate as a regional Exchange, fulfill the requirements under § 155.140, and meet the functional requirements in 45 CFR part 155 that are applicable to States who wish to operate their own SBE. We also note that HHS has provided the authority and flexibility for SBEs to utilize the direct enrollment pathway as an alternative option for enrolling consumers into SBEs. HHS continues to encourage SBEs and SBE–FPs to explore this option in the context of evaluating options that best suit the needs of their Exchange, State, and consumers.

b. Election To Operate an Exchange After 2014 (§ 155.106)

Section 155.106 describes the process for a State electing to operate a State Exchange, terminating its State Exchange and transitioning to an FFE, or seeking to operate an SBE–FP. This section applies to both individual market and SHOP Exchanges. Currently, under § 155.106(c), as finalized in the 2017 Payment Notice, States can elect to operate an individual market SBE–FP, an SBE–FP for SHOP, or both. If a State operates an SBE–FP for SHOP, the SBE–FP utilizes the Federal platform for enrollment, eligibility, and premium aggregation functions.

As discussed more fully in section III.D.9 of this final rule, we proposed changes to required SHOP functionality, effective on the effective date of this rule, for plan years beginning on or after January 1, 2018, under which qualified employers and employees could enroll in SHOP plans by working with a QHP issuer or SHOP-registered agent or broker. As a result of the finalization of these proposals, many Federal platform functions currently available to a State operating an SBE–FP for SHOP will no longer exist, including employee eligibility, enrollment, and premium aggregation functions. Therefore, States operating an SBE–FP for SHOP will no longer be able to utilize the Federal platform for those functions.

We proposed to amend § 155.106(c) to remove the option for States to seek approval to operate an SBE–FP for SHOP after the effective date of this rule, and are finalizing the policy as proposed. Nonetheless, States that are currently operating an SBE–FP for SHOP, which include Kentucky and Nevada, can choose to maintain their existing SBE–FPs for SHOP, using the Federal platform functionality that would remain, subject to the applicable requirements in § 155.200(f)(4), which we are amending to align with the changes to SHOP functionality requirements. Issuers in these SBE–FPs for SHOP will continue to be subject to § 156.350, which we are amending to align with the changes to SHOP functionality requirements. For those issuers that offer SHOP QHPs in SBE–FPs for SHOP beginning on or after January 1, 2018, the expected burden (as well as expected reduction in burden) should be similar to that of issuers in the FF–SHOPs.

Comment: One commenter suggested HHS should consider continuing to permit States to elect to operate as an SBE–FP for SHOP, to increase the type of Exchange models available to States. Otherwise, we did not receive substantive comments regarding the proposed changes to § 155.106.

Response: As described above, as a result of the finalization of the SHOP proposals described in this rule, the SHOP Federal platform currently available to a State operating an SBE–FP for SHOP will essentially no longer exist, including the Federal platform functions of employee eligibility, enrollment, and premium aggregation

on which SBE–FPs for SHOP currently rely. Therefore, States operating an SBE–FP for SHOP will no longer have an option to rely on the Federal platform for those functions. We are finalizing the policy as proposed, with a minor, non-substantive change to the regulatory text.

c. Additional Required Benefits (§ 155.170)

Section 1311(d)(3)(B) of the PPACA permits a State, at its option, to require QHPs to cover benefits in addition to the EHB, but requires a State to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional State-required benefits. In previous rulemaking, we directed States to identify additional State-required benefits that are subject to defrayal and provided direction on how QHP issuers in a State must calculate the cost of those benefits.[42]

We made a number of proposals at § 156.111 related to State changes to EHB-benchmark plans beginning for the 2019 plan year. In light of those proposed changes, we stated that we were not proposing any changes to the policies governing State-required benefits at § 155.170. That is, whether a benefit mandated by State action could be considered EHB would continue to depend on when the State enacted the mandate (unless the benefit mandated was for the purposes of compliance with Federal requirements). Under any of the proposed methods for a State to select a new EHB-benchmark plan, benefits mandated by a State action *prior to or on December 31, 2011* would be considered EHB in that State according to the continuing policy described above and would not require State defrayal. However, State-required benefits mandated by State action taking place *after December 31, 2011,* other than for purposes of compliance with Federal requirements, would continue to be considered in addition to EHB even if embedded in the State's newly selected EHB-benchmark plan under the proposals at § 156.111. Therefore, their costs would be required to be defrayed by the State.

As discussed more fully in the preamble for § 156.111, we proposed that § 155.170 would continue to apply in the same manner as it currently applies to § 156.110, and that the proposed § 156.111, which offers States the flexibility to select a new EHB-benchmark plan, would not remove the obligations required with regard to maximum allowed generosity for a State's EHB-benchmark plan. For further discussion of how the State mandate policy at § 155.170 would apply to EHB under the proposals at § 156.111 providing States with options to select a new EHB-benchmark plan for plan years beginning in 2020 and later, see the preamble to § 156.111.

We sought comments on this approach. Specifically, we were interested in comments on different applications of the State mandate policy to the proposed policy for EHB-benchmark plan selections at § 156.111 that would increase State flexibility while also being cost effective for States, consumers, and the Federal government, such as an approach that would allow States the flexibility to update benefits mandated by State action prior to or on December 31, 2011, that are considered EHB, so long as the State can prove that the update to the State mandate is budget neutral.

In this final rule, we are finalizing the approach described above of not making changes to the policy under § 155.170.

Comment: Many commenters requested changes to the policies governing State-required benefits at § 155.170 in light of new EHB-benchmark plan selection options established at § 156.111. Some of these commenters were concerned about States selecting a more generous benchmark plan under the proposed options at § 156.111(a) that could reduce affordability by allowing the selecting State to include another State's mandates in its benchmark plan and thereby allow the selecting State to indirectly adopt another State's mandates *without* defrayal. These commenters recommended that States be required to defray the costs of any additional required benefits that result from the selection of a new EHB-benchmark plan if those benefits are more generous than the State's previous EHB-benchmark plan, regardless of whether the additional benefits were put in place by the newly-selected EHB-benchmark plan or were the result of benefits mandated by State action in the selecting State. Other commenters were concerned that the current policy of requiring States to defray the costs of State-required benefits mandated after December 31, 2011, other than for purposes of compliance with Federal requirements, would prevent States from updating benefits in response to medical advances and their population's changing needs. These commenters requested that HHS create a public process for States to consider new State-required benefits as EHB without additional cost to the State. Other commenters opposed requiring States to defray mandated benefits at all, because the policy discourages States from ensuring access to key health care services for consumers—such as autism and opioid dependency disorder services. Several commenters supported the proposal to maintain the policies at § 155.170, noting that section 1302(b)(4)(H) of the PPACA grants the Secretary flexibility to update EHB benefit categories as it becomes necessary to do so. Other commenters believed that a stricter standard regarding defrayal is needed to ensure that States comply with the current defrayal requirement at § 155.170, and to ensure that a sufficient defrayal requirement is in place based on new State EHB-benchmark plan selection options at § 156.111.

Response: We understand the importance of benefit mandates to States under the policies described above. With the finalization of the State's new EHB-benchmark plan options at § 156.111, States will continue to have the authority to implement benefit mandates as part of EHB, in accordance with § 155.170.

Specifically, if a State selects a new EHB-benchmark plan under any of the options finalized in this rule at § 156.111, the benefits mandated by the selecting State's action prior to or on December 31, 2011 will continue to be considered EHB and will not be subject to defrayal, in accordance with § 155.170. If the State is selecting from another State's EHB-benchmark plan under the first or second option, as discussed in preamble to § 156.111, and the selected EHB-benchmark plan (or category of services) includes benefits mandated by the State from which the plan originated that are EHB, those benefits will also be incorporated into the selecting State's EHB-benchmark plan without a requirement that the selecting State defray their related costs, unless the selecting State has its own mandates regarding these same benefits and those mandates meet the requirements for defrayal in § 155.170.

Relatedly, our decision to maintain the policies governing State-required benefits at § 155.170 is motivated by our goal to provide States with more flexibility and reduce administrative burden for selecting a new EHB-benchmark plan under Option 1 or 2 described in § 156.111. Specifically, we believe that many benefits that are State mandates are likely already embedded

[42] *See* 155.170(b) and (c). *Also see* the EHB Rule, available at *https://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf*, the 2016 Payment Notice Final Rule, available at *https://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf,* and the 2017 Payment Notice Final Rule, available at *https://www.gpo.gov/fdsys/pkg/FR-2016-03-08/pdf/2016-04439.pdf.*

in States' existing 2017 EHB-benchmark plans, and removing them would be complicated for a selecting State. In particular, we are concerned that this additional level of effort would create a barrier to States trying to select another State's 2017 EHB-benchmark plan under Options 1 or 2 being finalized at § 156.111(a)(1) and (2), particularly when several types of benefits mandated by State action overlap with one of the ten EHB categories. More specifically, because benefits mandated by State action are generally EHB if the mandates were enacted on or before December 31, 2011, and the 2017 EHB-benchmark plans that are used for the options under § 156.111 are based on base-benchmark plans that were available in 2014, we believe that the majority of benefits mandated by State action that are EHB in accordance with § 155.170 are already embedded in the originating State's EHB-benchmark plan documents.

We also note that we are finalizing that all options for a State to select a new EHB-benchmark plan described in § 156.111 are limited by a generosity standard. This generosity standard will limit the State's ability to increase the overall scope of benefits in its EHB-benchmark plan beyond the generosity of a set of comparison plans that includes a State's 2017 EHB-benchmark plan and any of the State's base-benchmark plan options for the 2017 plan year described in § 156.100(a)(1), supplemented as necessary under § 156.110. In practice, this requirement limits States' overall ability to select a new EHB-benchmark plan that transfers benefits that were previously only applied to the State's large group market, or that were mandated by other States' actions prior to 2012, into its new EHB-benchmark plan. As a result, we believe that this approach balances our goal to promote State flexibility with the need to preserve coverage affordability. For additional discussion on considerations related to § 155.170 for States that select a new EHB-benchmark plan using an option described at § 156.111, see the preamble to section § 156.111.

3. General Functions of an Exchange

a. Functions of an Exchange (§ 155.200)

The 2017 Payment Notice finalized requirements at § 155.200(f)(2) for SBE–FPs to establish and oversee certain requirements for their QHPs and QHP issuers that are no less strict than the requirements that apply to QHPs and QHP issuers on an FFE. Due to the operational complexities in implementing these requirements from both the State and Federal perspective, and to promote the goal of returning regulatory authority over the insurance markets to States, we proposed to eliminate requirements for SBE–FPs to enforce FFE standards for network adequacy at § 155.200(f)(2)(ii) and essential community providers at § 155.200(f)(2)(iii). Instead, we proposed that the SBE–FPs, like other State Exchanges, would have the flexibility to determine how to implement the network adequacy and essential community provider (ECP) standards with which issuers offering QHPs through the SBE–FP must comply. We believe SBE–FPs are best positioned to determine these standards for the QHP certification process in their States, and that the removal of the requirement that SBE–FPs establish and oversee requirements for their issuers that are no less strict than the manner in which these regulatory requirements are applied to FFE issuers would streamline certain aspects of the QHP certification process, and return traditional insurance market regulatory authority to the States. Additionally, HHS proposed that, for 2019 plan years and later, the FFEs would rely on State reviews of network adequacy standards where the States have been determined to have an adequate review process. Accordingly, we believe similar deference should be granted to States with SBE–FPs. We believe these changes will further empower SBE–FPs to use their QHP certification authority to encourage issuers to stay in the Exchange, enter the Exchange for the first time, or expand into additional service areas. We are finalizing these changes as proposed.

We also proposed to remove the requirement at § 155.200(f)(2)(iv) that QHP issuers in SBE–FPs comply with the Federal meaningful difference standard to reflect the removal of § 156.298 described elsewhere in this rule. We are finalizing this change as proposed.

Comment: Several commenters opposed eliminating requirements for SBE–FPs to enforce FFE standards for network adequacy at § 155.200(f)(2)(ii) and ECPs at § 155.200(f)(2)(iii) for the 2019 benefit year and beyond. They urged HHS to continue requiring SBE–FPs to enforce these FFE standards, stating that some State Exchanges that do not currently use the Federal platform have adopted less robust network adequacy and ECP standards, which are critical to providing access to providers that serve vulnerable populations. Other commenters supported this proposal if the States have an adequate review process, and encouraged HHS to monitor State oversight of networks to ensure that the States in fact have the capacity to ensure health plan compliance. Other commenters supported this proposal, stating that they believe networks are best developed and regulated at the State level to allow for variations in State geography, demographics, and market conditions.

Response: We are finalizing the proposal to remove the requirement that SBE–FPs establish and oversee requirements for their issuers that are no less strict than the manner in which these regulatory requirements are applied to FFE issuers. We believe SBE–FPs are best positioned to determine these standards for the QHP certification process in their States, and elimination of this requirement would streamline certain aspects of the QHP certification process by reducing oversight burden on SBE–FPs.

Section 155.200(f)(4) describes requirements for States that operate an SBE–FP for SHOP. As discussed earlier in this preamble, although we proposed that States can no longer elect to operate SBE–FPs for SHOP after the effective date of this rule, which we are finalizing as proposed, Kentucky and Nevada are already approved to operate SBE–FPs for SHOP, and thus the requirements in § 155.200(f)(4) remain relevant for those SBE–FPs for SHOP. Therefore, we proposed to amend § 155.200(f)(4) to reflect the proposed amendments (described in section III.D.9 of this final rule) under which the functionality of the FF–SHOPs' platform would be reduced for plan years beginning on or after January 1, 2018. Specifically, we proposed to amend the introductory text to § 155.200(f)(4) to describe the requirement applicable, effective on the effective date of this rule for plan years beginning on January 1, 2018 and beyond, and to make the requirements in paragraphs (f)(4)(i) through (vii), effective on the effective date of this rule applicable for only plan years beginning prior to January 1, 2018.

Specifically the requirements in (f)(4)(i) and (iv), which require SBE–FPs for SHOP to align their premium payment and employer contribution calculation methodologies with those used by the Federal platform, would not apply for plan years beginning on or after January 1, 2018, effective on the effective date of this rule. Because under our amendments to § 155.705 and newly finalized § 155.706, for plan years beginning on or after January 1, 2018, the Federal platform for SHOP will no longer calculate premium rates or employer contributions, and will no longer aggregate premium payments (as of the effective date of the final rule),

there will be no further need for such alignment for plan years beginning on or after January 1, 2018.

Because under the approach we are finalizing, the Federal platform will continue to include plan display with premium amounts, we did not propose changes to the requirement that States operating an SBE–FP must require its QHP issuers to make any changes to rates in accordance with the timeline applicable in a Federally-facilitated SHOP under current § 155.705(b)(6)(i)(A), which regulation is mirrored in our proposed introduction of § 155.706(b)(6)(i)(A). However, we proposed to specify that this requirement applies in the introductory text to (f)(4), to reflect the proposed change to make the requirements in (f)(4)(i) through (vii) applicable for only plan years beginning prior to January 1, 2018, effective on the effective date of this rule.

Additionally, because under the approach we are finalizing, for plan years beginning on or after January 1, 2018, the Federal platform will, effective on the effective date of this rule no longer calculate whether a qualified employer has met the applicable minimum participation rate, there will no longer be any need for States operating an SBE–FP for SHOP to align their minimum participation rate requirements and calculation methodologies with those applicable in the FF–SHOPs for plan years beginning on or after January 1, 2018. Therefore, we proposed that this requirement would only apply for plan years beginning prior to January 1, 2018, effective on the effective date of this rule.

To align with our amendments at § 155.725 and newly finalized § 155.726, under which the FF–SHOPs, effective on the effective date of this rule, for plan years beginning on or after January 1, 2018, will no longer establish annual employee open enrollment periods, or establish effective dates of coverage for an initial group enrollment or group renewal, we also proposed that the requirements in § 155.200(f)(4)(v) and (vi) would only apply for plan years beginning prior to January 1, 2018, effective on the effective date of this rule. Finally, to align with our amendments at § 155.735, under which the FF–SHOP, effective on the effective date of this rule for plan years beginning on or after January 1, 2018, will no longer determine the timing, form, and manner in which coverage or enrollment in a SHOP QHP may be terminated, we proposed that the requirement in § 155.200(f)(4)(vii) would only apply for plan years beginning prior to January 1, 2018, effective on the effective date of this rule.

We are finalizing as proposed the changes to § 155.200. Substantive comments related to SHOP proposals are summarized in section III.D.9 of this final rule.

b. Navigator Program Standards (§ 155.210)

Each Exchange is required under section 1311(d)(4)(K) and 1311(i) of the PPACA to establish a Navigator program under which it awards grants to entities that, among other things: Conduct public education activities to raise awareness of the availability of QHPs, distribute fair and impartial information concerning enrollment in QHPs and the availability of PTCs and CSRs, and facilitate enrollment in QHPs. Under section 1311(i)(2)(B) of the PPACA, these entities may include trade, industry, and professional associations; commercial fishing industry organizations; ranching and farming organizations; community and consumer-focused nonprofit groups; chambers of commerce; unions; resource partners of the Small Business Administration; other licensed insurance agents and brokers; and other entities that meet the statutory requirements at section 1311(i)(3), (4), and (5) of the PPACA.

Currently, § 155.210(c)(2) specifies that each Exchange must include among its Navigator grantees both a community and consumer-focused nonprofit group and at least one other entity that is from one of the other categories listed at § 155.210(c)(2), including other public or private entities or individuals that meet the requirements of § 155.210. Section 155.210(c)(2)(viii) specifies that these other entities may include Indian tribes, tribal organizations, urban Indian organizations, and State or local human service agencies.

To maximize the flexibility and efficiency of the Navigator program, we proposed to amend § 155.210(c)(2) to remove the requirements that each Exchange must have at least two Navigator entities and that one of these entities must be a community and consumer-focused nonprofit group. As discussed further below, we are finalizing this amendment as proposed. We believe removing these requirements will provide Exchanges with improved flexibility to award funding to the number and type of entities that will be most effective for the specific Exchange. We believe that eliminating the requirement to have at least two Navigator entities will allow each Exchange to optimally use the funding amounts available to direct investments to effective and efficient Navigators, which may include selecting a single, high performing grantee in an Exchange.

The requirement that one Navigator grantee in each Exchange must be a community and consumer-focused nonprofit group may unnecessarily limit an Exchange's ability to award grants to the strongest applicants, particularly in an Exchange that opts under this final rule to have only one Navigator grantee and where the strongest applicant is not a community and consumer-focused nonprofit group. Keeping this requirement would effectively exclude any other type of statutorily eligible entities from becoming Navigators in an Exchange that opts to have only one Navigator grantee. Eliminating this requirement will provide Exchanges with the flexibility to target grants to the highest scoring and performing entities, regardless of organization type.

Removing these requirements at § 155.210(c)(2) will also promote Exchange flexibility and autonomy to structure Navigator programs tailored to each Exchange. An Exchange could award a grant to a single Navigator entity from any of the permitted types. Alternatively, Exchanges could elect to continue awarding two or more grants, as they have been doing thus far, and include a community and consumer-focused nonprofit group among those grantees.

Section 155.210(e)(7) requires each Navigator entity to maintain a physical presence in the Exchange service area, so that face-to-face assistance can be provided to applicants and enrollees. We proposed to remove this requirement to provide more flexibility to each Exchange to structure its Navigator program to best serve the Exchange service area, and as discussed further below, are finalizing this amendment as proposed. Under section 1311(i)(2)(A) of the PPACA and § 155.210(c)(1)(ii), entities seeking to become Navigator grantees must demonstrate to the Exchange that they have existing relationships, or could readily establish relationships, with employers and employees, consumers (including uninsured and underinsured consumers), or self-employed individuals likely to be eligible for enrollment in a QHP. Consistent with those provisions, Navigator grant applicants in the FFEs are scored on their ability to make this demonstration. Based on HHS's experience with Navigator programs in FFEs and other public programs, we believe entities with strong relationships in their FFE service areas tend to deliver the most effective outreach and enrollment

results. However, we believe that each Exchange is best suited to determine the weight to give a physical presence in the Exchange service area when selecting Navigator entities, as long as the Exchange's Navigator grantee selection process is consistent with section 1311(i)(2)(A) of the PPACA and § 155.210(c)(1)(ii).

For reasons similar to those motivating our proposed changes to § 155.210(e)(7), as well as to promote consistency across programs, we proposed to remove the corresponding requirement at § 155.215(h) that requires maintenance of a physical presence in the Exchange service area by all non-Navigator entities subject to § 155.215. We are also finalizing this amendment as proposed.

In addition to the requirement to maintain a physical presence in the Exchange service area, §§ 155.210(e)(7) and 155.215(h) currently provide that, in an FFE, no individual or entity is ineligible to operate as a Navigator or non-Navigator assistance personnel solely because its principal place of business is outside of the Exchange service area. We did not propose to amend or remove that language, and it will remain in effect.

In addition to seeking comment on the proposed amendments described above, we also sought comment on statutorily acceptable alternative types of entities that could serve as Navigators and on possible new ways in which Navigators could carry out their duties.

Comment: We received comments in support of removing the requirement that each Exchange must have at least two Navigator entities. Several commenters believed that adopting this change could assist HHS with ensuring that Navigator grants are expended efficiently and effectively. Many commenters, however, expressed concern about reducing the number of required Navigator entities per Exchange, conveying that removing this requirement could potentially negatively affect consumer access to in-person assistance, and therefore make it harder for consumers to understand their coverage options and enroll in health coverage. Several commenters suggested that having two Navigator entities per Exchange ensures that an Exchange can have a general entity and one more tailored to specific needs within an Exchange, such as a focus on young adults, limited English proficient individuals, or other targeted populations.

Response: We agree with commenters who stated that removing these requirements will provide Exchanges with improved flexibility to award funding to the number and type of entities that would be most effective for each specific Exchange. We appreciate the importance of consumer access to experienced, in-person assistance, and believe this change will allow each Exchange to optimally use available funding amounts, such as by selecting a single, high-performing grantee in an Exchange. In this way, we do not believe this change will have a detrimental effect on the availability of professional, unbiased, in-person consumer assistance. Additionally, the proposal does not require an Exchange to have only one Navigator. It simply provides Exchanges with that option. We are finalizing this change as proposed.

Comment: We received comments in support of removing the requirement that each Exchange must have one Navigator entity that is a community and consumer-focused nonprofit. Several of these commenters supported HHS's promotion of Exchange flexibility with this change. However, many commenters expressed concern about removing this requirement, conveying that Navigators, and in particular independent, nonprofit Navigators, have proven to be a critical resource for helping consumers enroll in coverage that is appropriate for their needs in previous enrollment periods. Many commenters stated that nonprofit Navigator entities are unique among other types of Navigator groups because they typically have expertise with one or more hard-to-reach populations within their communities, such as veterans, limited English proficiency individuals, or other targeted populations, and have the trust of many community members. In addition, commenters suggested that this requirement was initially added to address concerns about fraud, abuse, and the difficulty that Exchanges faced overseeing other types of Navigator entities.

Response: We agree with commenters who emphasized the importance of funding nonprofit Navigator entities, and also agree that nonprofit Navigator entities often have expertise with one or more hard-to-reach populations within their communities. Nothing in this rule prevents an Exchange from selecting and funding a nonprofit Navigator entity if it determines that such an entity best meets the needs of the community served by the Exchange. However, we also recognize that there are circumstances in which another type of entity may be the strongest applicant. In these cases, an Exchange that chooses to have only one Navigator grantee (as permitted by the change finalized in this rule), would be unable to select its strongest applicant absent a change to the requirement that one Navigator grantee in each Exchange must be a community and consumer-focused nonprofit group. We also agree with commenters that removing this requirement will support Exchange flexibility and autonomy to structure Navigator programs tailored to each Exchange and target grants to the highest scoring and performing entities, regardless of organization type. We believe that Exchanges are well-situated to determine the proper use of the funding amounts available and are able to determine the type of entity or entities that will serve their Exchange service areas best. We are finalizing this change as proposed.

Comment: We received comments in support of removing the standard requiring Navigators to maintain a physical presence in the Exchange service area. Several commenters believed that removing this requirement will provide Exchanges with greater flexibility and enable them to expand options for consumer support. On the other hand, many commenters believed that entities not physically present in an Exchange service area may not be able to provide a full spectrum of local outreach, education, and assistance to support enrollment and post-enrollment activities. Many commenters suggested that removing this requirement would negatively affect hard-to-reach populations, as the in-person assistance provided by Navigator entities is often the only known resource and form of support for some low-income and other at-risk populations. In addition, some commenters believe that web or phone-based assistance is a poor substitute for in-person assistance delivered by a known and trusted community-based organization, and that this is particularly true for those living with significant health needs for whom remote assistance may prove inadequate and frustrating.

Response: We agree with commenters who emphasized the importance of providing more flexibility to each Exchange to structure its Navigator program to best serve the Exchange's service area. As we stated in the proposed rule, we believe that entities with a physical presence and strong relationships in their FFE service areas tend to deliver the most effective outreach and enrollment results. Nothing in this final rule prevents an Exchange from selecting grantees that are physically present and available to provide a spectrum of in-person, local outreach, education, and assistance, including directing these services

towards vulnerable and hard-to-reach populations, if the Exchange elects to weight its selection process in that way and its selection process is consistent with section 1311(i)(2)(A) of PPACA and § 155.210(c)(1)(ii). Furthermore, we believe that there are various organizations that might prove to be promising partners in the delivery of both local and remote consumer assistance with regard to health coverage enrollment and education. While in-person assistance may be more helpful than remote services in some situations, we believe that determining which entities are well-situated to serve consumers within a particular Exchange is best left up to each Exchange. By allowing Exchanges greater flexibility, each Exchange will be better able to ensure that its service area can be assisted by the entity or entities that best fits the needs of its population. We are finalizing this change as proposed.

Comment: We received comments about the potential use of other entities to provide enrollment assistance or remote services to consumers, beyond Navigator entities. Some commenters conveyed that other types of organizations are well-situated to provide enrollment assistance, such as local agents and brokers and direct enrollment partners. Some commenters believe that an approach to consumer assistance that leverages experts from different types of organizations that have strong ties to the community is a comprehensive way to provide consumers with the best available expertise.

Response: We agree that local collaboration and leveraging community partnerships can help in reaching marginalized communities. For FFEs, we will take these comments into consideration when drafting Navigator selection criteria for Navigator funding opportunity announcements in future years. While agents, brokers, and direct enrollment partners might in many cases not be eligible to become Navigators due to statutory limitations on Navigator eligibility at section 1311(i)(4) of PPACA, we also agree that agents, brokers, and direct enrollment partners can be well situated to provide enrollment assistance or remote services to consumers, and we intend to continue to work with these stakeholders to ensure consumers in FFEs have access to a range of enrollment assistance, including Navigators.

c. Standards Applicable to Navigators and Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under §§ 155.205(d) and (e) and 155.210 in a Federally-Facilitated Exchange and to Non-Navigator Assistance Personnel Funded Through an Exchange Establishment Grant (§ 155.215)

For a discussion of the provisions of this final rule related to standards applicable to non-Navigator Assistance Personnel subject to § 155.215, please see the preamble to § 155.210.

d. Standards for Third-Party Entities To Perform Audits of Agents, Brokers, and Issuers Participating in Direct Enrollment (§ 155.221)

HHS proposed new standards in the proposed rule to replace the standards set forth in the 2018 Payment Notice for § 155.221 for third-party onboarding operational readiness reviews and audits for direct enrollment partners. HHS also proposed to expand the applicability of this section to require issuers, in addition to agents and brokers, participating in direct enrollment to engage third-party entities to conduct the required operational readiness reviews. We proposed a conforming edit to § 156.1230(b)(2) to reflect this proposal.

HHS proposed to implement an approach wherein agents, brokers, and issuers that participate in direct enrollment and use their own internet website for QHP selection or to complete the Exchange eligibility application would select their own third-party entities for conducting audits, rather than requiring HHS to initially review and approve these entities. As detailed in the proposed rule, HHS anticipates this approach would reduce the regulatory burden for agents, brokers, and issuers, and reduce duplicative HHS oversight. This approach will also reduce the burden on third-party entity reviewers.

Beginning with the open enrollment period for the 2019 benefit year, we proposed that an agent, broker, or issuer must engage a third-party entity that meets the standards outlined in the new § 155.221(b) to conduct an annual operational readiness review prior to participating in direct enrollment. Consistent with § 155.220(c)(3)(i)(K) and § 156.1230(b)(2), the operational readiness review would be performed using the third parties' own audit processes and methods subject to HHS-defined specifications and requirements. The third-party entity's review would verify compliance by the agent, broker, or issuer with the applicable requirements in §§ 155.220, 155.260, 156.265, and 156.1230, and would need to be completed prior to the use of the agent, broker, or issuer internet website for submission of an Exchange application or completion of QHP selection. HHS would publish technical guidance outlining the review standards and other operational details, as well as provide other resources to assist the third-party entities in conducting the reviews at a later date. As outlined in the last sentence of the new § 155.221(a), the third-party entity would be a downstream or delegated entity of the agent, broker, or issuer that participates or wishes to participate in direct enrollment. Therefore, these third-party entities would be subject to HHS oversight as delegated or downstream entities of an agent, broker, or issuer, and the agent, broker, or issuer will remain responsible for compliance with all applicable direct enrollment requirements.

We also proposed revisions to § 155.221(b), which establishes standards that third-party entities must satisfy to perform the reviews to demonstrate operational readiness under § 155.220(c)(3)(i)(K) and § 156.1230(b)(2), beginning with the open enrollment period for the 2019 benefit year. The proposed new introductory language at § 155.221(b) aligns with the new approach where the agent, broker, or issuer selects the third-party entity to perform the audit under paragraph (a). As proposed, new § 155.221(b)(1) would require the entity to have experience conducting audits or similar services, including specific experience with relevant privacy and security standards due to the operational requirements of the current direct enrollment processes and any potential future enhancements. This would include demonstrated experience with current National Institute of Standards and Technology (NIST) SP 800–53 or the HIPAA Security Rule standards, and the review of compliance with those standards. We proposed that auditors must also be capable of performing penetration testing on all interfaces that collect personally identifiable information or connect with HHS. We proposed to modify § 155.221(b)(2) to include issuers participating in direct enrollment and to expand the scope of the audit to also include review of compliance with other applicable program requirements (for example, website design, or consumer disclosures). Under proposed § 155.221(b)(3), auditors would be required to collect, store, and share with HHS all data related to its audits of

agents, brokers, and issuers under paragraph (a) in a manner, format, and frequency specified by HHS until 10 years from the date of creation, and would be required to comply with the privacy and security standards HHS adopts for agents, brokers, and issuers as required in accordance with § 155.260.

The proposed revisions to paragraph (b)(4) would implement a conflict of interest standard that requires disclosure of financial relationships between a third-party entity conducting a direct enrollment operational readiness review and the agent, broker, or issuer. In addition, the third-party entity would be required, under § 155.221(b)(5), to comply with all applicable Federal and State requirements; under § 155.221(b)(6), to ensure, on an annual basis, that appropriate staff successfully complete operational readiness review training as established by HHS prior to conducting audits under paragraph (a) of this section; and, under § 155.221(b)(7), to permit access by the Secretary and the Office of the Inspector General (OIG), or their designees, in connection with their right to evaluate through audit, inspection, or other means, to the third-party entity's books, contracts, computers, or other electronic systems, relating to the third-party entity's audits of agents, broker's, or issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the date of creation. Finally, to provide flexibility, under § 155.221(c) an agent, broker, or issuer would be permitted to engage multiple third-party entities to perform the audits under paragraph (a) and each such third-party entity would need to separately comply with the standards under paragraph (b). We are finalizing these amendments as proposed, with a minor, non-substantive change described below.

Comment: Most commenters were concerned that enrollment through a non-governmental site would occur without proper oversight and controls. They expressed concern about the potential for fraud, or the possibility that agents, brokers, and issuers would unfairly direct consumers to QHPs with which the agent, broker, or issuer, had an existing relationship. Additionally, a number of commenters were concerned about the potential for conflicts of interest arising from relationships between the agents, brokers, and issuers and the third-party auditors they select to conduct their audits.

Response: We are finalizing the modifications to § 155.221 as proposed, with a minor non-substantive edit to paragraph (b)(7) to remove the acronym ''OIG''. We have put in place guidelines and processes to oversee the activities of agents, brokers, and issuers participating in direct enrollment, and anticipate continuing to monitor enrollments through the direct enrollment pathway for evidence of fraud or abuse. While we acknowledge the potential for conflicts of interest, we believe the required disclosures, continuous monitoring and oversight, and standards established for third-party auditors will sufficiently mitigate these concerns. Furthermore, we believe the requirements being finalized in this rule will ensure that quality operational readiness reviews are conducted. Lastly, we agree that it is important that consumers enrolling using direct enrollment be able to make informed decisions about coverage. We believe § 155.220, which establishes standards that apply when Exchange consumers select an individual market QHP through an agent's or broker's website, including a requirement that agents and brokers engaged in direct enrollment display all QHP data provided by the Exchange, will help promote informed consumer choice about all available QHPs, not just those with which the agent or broker has an existing relationship.

4. Exchange Functions in the Individual Market: Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

a. Eligibility Standards (§ 155.305)

Section 155.305(f)(4)(i) prohibits an Exchange from determining a consumer eligible for APTC if APTC payments were made on behalf of the tax filer for the consumer's household (or either spouse, if the tax filer is married) for a previous year for which tax data would be used for verification of household income and family size, and the tax filer or his or her spouse did not comply with the requirement to file an income tax return and reconcile APTC paid on their behalf that year. Under the current regulation at paragraph (f)(4)(ii), Exchanges cannot discontinue APTC due to a failure to file and reconcile (FTR) associated APTC unless direct notification is first sent to the tax filer that his or her eligibility will be discontinued as a result of the tax filer's failure to comply with the requirement specified under paragraph (f)(4)(i) of § 155.305.

We proposed to amend § 155.305(f)(4) by removing the direct notification requirement in paragraph (f)(4)(ii) and revising the remaining paragraph (f)(4) to move the content in paragraph (f)(4)(i) into paragraph (f)(4).

We are finalizing this policy as proposed.

Comment: Nearly all commenters on this issue expressed concern that relying on a notice that is not explicit to inform consumers that APTC eligibility may be discontinued—without giving consumers the specific reason and clearly instructing them how to correct the issue—is insufficient to ensure those wishing to continue their eligibility have the necessary information to do so. A few commenters stated that FFE [43] notices are often difficult for consumers to understand, and consumers often bring their notices to assisters for help understanding them. One commenter stated that this confusion can be compounded for non-English or non-Spanish speakers, who often are unable to understand notices because they are unable to read them and may not take the notices to an enrollment assister or otherwise have the notice translated in time to take the appropriate action. One commenter recommended Exchanges send multiple notices regarding failure to file and reconcile to affected consumers and tax filers.

Response: We recognize that describing complex information about eligibility for APTC to consumers involves a complicated balance between providing complete and accurate information, and being clear and concise enough that the consumer is likely to read and understand the information. Understanding this information can be especially challenging for non-English speakers. Exchanges must notify consumers when they make eligibility determinations based on FTR, but rules on the disclosure of Federal tax information (FTI) present significant challenges in communicating with this population. Historically, all communications regarding FFE applicants and enrollees are addressed to the household contact, who in most cases is the tax filer for the applicants on the relevant application. Internal Revenue Service (IRS) rules generally prohibit the disclosure of FTI to anyone other than the tax filer, and FTI includes all information from a tax return, including information as to whether a tax return has been filed with IRS. Also considered FTI is any list that is generated based only on information that is FTI itself. For example, a list of consumers who have not filed a tax return is considered FTI. The FFE's current noticing infrastructure does not

[43] All Exchanges using the Federal eligibility and enrollment platform, including SBE–FPs, take the same approach to handling FTR associated APTC. Therefore, in this section, the term ''FFE'' describes all Exchanges using the Federal eligibility and enrollment platform.

have FTI privacy safeguards built into its system to send notices to tax filers (as distinct from the household contact), to store notices in a manner compliant with required protections for FTI, or to establish user permissions for approved Exchange and Exchange contractor personnel only to access these notices for operationally necessary purposes, such as Call Center support, casework, or appeals.

To avoid unauthorized disclosure of FTI to individuals who are not the relevant tax filer, the FFE sends notices to FTR and non-FTR consumers that contain language regarding FTR, but also language that is broad enough to apply to all consumers who receive them; these notices are referred to as ''combined notices.'' For example, the FFE sends the same Marketplace Open Enrollment Notice to three groups of consumers at risk for APTC discontinuation in the upcoming coverage year: Those flagged as FTR, those for whom the FFE has received updated income information that suggests the consumers may have income too high to qualify for APTC, and those who did not permit the Exchange to check IRS data. Because the combined notices apply and are sent to some consumers who are currently unaffected by FTR, and not exclusively to individuals who are affected by FTR, these notices are not considered FTI under IRS rules and are able to be sent using the standard FFE notice functionality.

To supplement the combined notice, in November 2017, the FFE also mailed warning notices that complied with FTI rules to tax filers on whose behalf APTC was being paid but for whom the FFE had information the tax filer had not met the requirement to file and reconcile. These notices, which we refer to as ''direct notices,'' urged the tax filers to file and reconcile to avoid losing APTC starting in January 2018. To comply with FTI requirements, the direct notices were not generated by the FFE itself; rather, data was securely sent to an FTI-compliant print contractor for printing and mailing. In order to be FTI-compliant—including being accessible only to the tax filer—direct notices are not available through the online Exchange account for the application.

We intend for the FFE to continue sending two notices in advance of open enrollment where the Exchange has information that the tax filer on whose behalf APTC is being paid has failed to meet the requirement to file and reconcile: (1) A combined notice provided according to the communication preference set for the household contact (electronic or via U.S. mail) that will be available in consumers' online accounts and to the Exchange call center; and (2) a direct notice sent via U.S. mail to the tax filer that is not available electronically in the household's online account or to the Exchange call center, in order to protect FTI. The direct notice serves to unambiguously explain that the tax filer has been identified as having failed to meet the requirement to file and reconcile and must come into compliance to avoid termination of APTC. In 2018, the FFE will also send a combined notice and a direct notice in connection with its periodic check of tax data described in § 155.330(e)(2)(iii)(B). As commenters noted, we believe sending more than one notice may increase the likelihood that consumers identify and read the notices and ultimately take action.

Comment: Many commenters disagreed with our suggestion that a success rate of 60 percent of FFE household tax filers taking appropriate action to file and reconcile in response to the combined notices was sufficient and stated that 40 percent of households failing to take appropriate action demonstrates the lack of clarity the combined noticing approach creates among consumers.

Response: We agree that there is room for improvement on a success rate of 60 percent. We foresee this success rate rising as the Exchanges mature and consumers become more familiar with the requirement to file and reconcile, and as the FFE continues pairing the combined notices with direct notices to tax filers that more explicitly address the requirement to file and reconcile.

Comment: Many commenters were concerned that our proposal to remove § 155.305(f)(4)(ii) does not comply with constitutional due process rights—stating that when determining a tax filer ineligible to continue receiving APTC, Exchanges must issue a direct individual notice that contains a statement of the intended action, reasons for the action, specific legal support for the action, an explanation of the individual's hearing rights, and rights to representation and to continued benefits. They expressed concerns about consumer confusion given that neither the FFE's combined (non-FTI) notices nor follow-up through the call center can give consumers definitive guidance on their household tax filer's current tax filing status, whether they will be redetermined ineligible for APTC for the upcoming benefit year (and why), how to correct the problem, or how to challenge a redetermination of eligibility for APTC.

Response: We recognize there are limitations with the combined notices, which are unable to be explicit; however, this approach may be the only option available to many State Exchanges whose systems (including notice functionality) were not built for FTI compliance, and for which costly and time-consuming infrastructure upgrades are infeasible in the short term. As described previously, the FFE has begun mailing FTI-compliant direct notices to tax filers that contain a statement of the intended action, reasons for the action including regulatory support for the action, and an explanation of the individual's appeal rights if APTC is discontinued. While the FFE has been able to develop this workaround to provide FTI-compliant notices directly to tax filers, SBEs may have fewer options available to them. While some SBEs may be able to contract with the FFE's print contractor or another FTI-compliant contractor, we have heard that some are required to use only in-State contractors, which can create a significant barrier if there are no FTI-compliant contractors in the State.

We agree with commenters that it is important for all Exchanges to protect consumers' due process rights. Even in the case of an Exchange that cannot arrange to send direct notices that explicitly address FTR to the tax filer and that is limited to the combined notice approach, we believe there are adequate protections for due process. First, the tax filer still has an opportunity before the Exchange redetermines eligibility to file a tax return (or an amended tax return, as applicable) and reconcile APTC paid for the relevant benefit and tax year. We expect Exchanges to send appropriate notices to households affected by FTR that alert the tax filer that FTR may be the reason enrollees' eligibility for APTC is at risk. Second, for enrollees whose eligibility for APTC is terminated as a result of FTR, the enrollee will receive an updated eligibility determination notice that contains a full explanation of appeal rights. Enrollees who appeal may request to continue receiving financial assistance during the appeal, consistent with § 155.525. We believe these measures, including the option to maintain eligibility during an appeal, are consistent with due process.

Comment: Some commenters stated that tax filers have a property interest in the continued receipt of APTC for which they are eligible, and challenged our belief that the financial and operational burden for the Exchange of establishing a mechanism to notify tax filers without making an unauthorized disclosure of protected FTI would be

out of proportion with the limited need for FTI handling in Exchange operations, including generating notices. Some referenced a Federal judicial decision [44] stating that the ''public interest in assuring that health benefits will not be erroneously terminated or denied outweighs the State's competing fiscal and administrative concerns. Any inconvenience the State might suffer is out-balanced by the State's and the recipient's interest in providing health benefits to those who cannot otherwise afford them.''

One SBE supported the proposal to remove the direct notification provision in § 155.305(f)(4)(ii), citing significant implementation challenges to communicate with consumers without violating IRS's FTI security protections. It stated that current FTR processes and notifications being implemented by most Exchanges provide adequate notice to consumers.

Response: HHS is committed to ensuring consumers eligible for APTC maintain that important benefit; however, we also believe that ensuring consumers are not receiving APTC improperly is necessary for program integrity. Additionally, it is important to reduce burden on Exchanges, which have varying capacities. Establishing a mechanism through which to notify tax filers without making an unauthorized disclosure of protected FTI is a heavy undertaking for an Exchange if its notification system was not originally designed with that capability in mind. For the FFE, it would involve not only changes to its notice generation and storage infrastructure, including enhancements to segregate and secure FTI data, but also substantial modification to its entire account creation framework.[45] For a number of SBEs, upgrading their systems to be FTI compliant represents an undertaking that may be infeasible to implement in the short term. SBEs may also be unable to take the FFE's dual noticing approach because of limited print contracting options, as discussed above. The FFE plans to continue sending direct notices to tax filers to supplement the combined notices; we encourage SBEs to take a similar noticing approach, where feasible. We are available to provide technical assistance, as needed.

Comment: A few commenters recommended more research be done prior to the rule change. One commenter suggested we learn more about why taxes are not being filed in a timely way, suggesting there may be many reasons for non-compliance, and that this additional understanding could inform appropriate Exchange and IRS policies. Other commenters recommended we retain the current rule until we understand the impact of the new direct notice mailed in November 2017 to FFE enrollee tax filers affected by FTR. They suggested that, following the open enrollment period for 2018, we should assess whether there was an increase in the proportion of tax filers who took the necessary action to file their tax return and reconcile APTC, and a decrease in consumer confusion (for example, evidenced by the number of FTR-related call center questions), and consider whether any change is due to the cumulative impact of the two notices before finalizing any regulatory changes related to FTR procedures.

Response: We agree that gathering data on the effectiveness of FTR notices is a worthwhile endeavor, and we look forward to analyzing the numbers as suggested by the commenter, now that the open enrollment period for 2018 coverage is closed, to determine if recent messaging increased compliance and reduced the discontinuation of APTC as a result of FTR. However, we believe this regulatory change must be implemented in the short term in the interest of program integrity and to reduce burden on Exchanges.

Comment: A few commenters discussed the limitations when the household tax filer (to whom the FFE sent the direct notice in November 2017) does not reside with the household contact on the application (to whom the FFE sent the combined Marketplace Open Enrollment Notice in October 2017), which could hinder the affected individual's ability to understand the totality of the circumstances, and disagreed with our assumption that the household contact is likely to share the combined notice with the tax filer, since not all household contacts and tax filers on an application can readily and easily communicate with one another, including during medical or other emergency situations, death, separation or divorce, domestic abuse, or spousal abandonment. One commenter suggested that the combined notice sent to the household contact explain that the specific reason for the potential discontinuation of APTC will be contained in the direct notice to the tax filer. This commenter further suggested that the mailing addresses be verified against the United States Postal Service National Change of Address Database to help ensure deliverability, and that the envelopes be conspicuous to signify their importance (for example, red in color).

Response: We recognize there are household circumstances in which the tax filer and the household contact on the application do not live together. However, our data show that for 2017 and 2018 applications for which any amount of APTC was paid, 99.8 percent of household contacts listed on the application were also the tax filer. We agree that adding language to the combined notice pointing to the direct notice for additional specifics may help increase the likelihood that the tax filer fully understands the risk to continued APTC eligibility for enrollees in the household, and we may explore this approach through discussions with IRS regarding any potential FTI concerns. The FTI-compliant print contractor used by the FFE in November 2017 does verify addresses against the USPS National Change of Address Database, and we acknowledge that making envelopes more conspicuous could help ensure FTR notices are opened and read by consumers.

When consumers submit an FFE application, the filer of the application must agree to a statement that he or she has obtained consent for all people listed on the application for their information to be used for eligibility determination purposes, including verifying this information using the Exchange's trusted electronic data sources. In addition, following application submission and when selecting a plan and choosing the amount of APTC to apply to the monthly premium, the tax filer is required to agree to a statement that he or she must file a tax return for the year during which APTC is paid on his or her behalf (or on behalf of his or her spouse) and to reconcile those payments with IRS. The filer of the application specifies the contact person for Exchange communications (the household contact), as well as the method of communication they prefer—either electronic or via U.S. mail to the address they enter on the application. Because this household contact is designated as the point of contact for the enrollee(s) on the application, we

[44] *Rodriguez by and through Corella* v. *Chen*, 985 F.Supp. 1189 (D. Ariz. 1996).

[45] The FFE's current workaround of sending print-only FTI notices directly to tax filers is being performed outside of the FFE's standard notice processes, which allow household contacts to be notified according to their communication preferences (U.S. mail or electronic) and provides availability of all notices in consumers' online accounts. At a minimum, enhancements to the FFE's identity proofing requirements for all FFE accounts would be required in order to prevent disclosure of FTI information to anyone except the tax filer. Further, the call center's identity proofing practices and data systems would need to be enhanced to safeguard the information to an FTI standard, in order to continue assisting consumers with the application and enrollment process.

believe it is reasonable to assume he or she intends to receive communications about enrollees' eligibility for and enrollment in health coverage through the Exchange. Further, as this designated point of contact for Exchange enrollees, we believe this household contact would likely read these communications, and if their content discussed risk for financial assistance loss, share with the tax filer in the rare case that he or she is not the tax filer. We further believe it is reasonable to assume that the tax filer—if not the household contact—would be in contact with the Exchange enrollees for whom he or she is responsible with respect to tax filing, managing communications related to health coverage through the Exchange, or both.

We are finalizing these provisions as proposed, but remain committed to improving the clarity and effectiveness of the FTR notification process in circumstances where the Exchange has information that the tax filer has failed to file and reconcile.

b. Verification Process Related to Eligibility for Insurance Affordability Programs (§ 155.320)

i. Income Inconsistencies (§ 155.320(c))

Section § 155.320(c)(3)(iii) sets forth the verification process for increases in household income. Generally, if income data from our electronic data sources indicate a tax filer's attested projected annual income is *more than* the income amount represented by income data returned by the IRS and the SSA and current income data sources, § 155.320(c)(3)(iii) requires the Exchange to accept the attestation without further verification. Currently, Exchanges generally are not permitted to create inconsistencies (data matching issues) for consumers when the consumer's attested income is greater than the amount represented by income data returned by IRS and the SSA and current income data sources.

We proposed to revise § 155.320(c)(3)(iii) to specify that the Exchange will generate annual income inconsistencies in certain circumstances when a tax filer's attested projected annual income is *greater than* the income amount represented by income data returned by IRS and the SSA and current income data sources. Current regulations generally require the Exchange to accept a consumer's attestation to projected annual household income when the attestation reflects a higher income than what is indicated in data from the IRS and Social Security Administration. This approach makes sense from a program integrity perspective when both the attestation and data from trusted data sources are over 100 percent Federal poverty level (FPL), since an attestation that is higher than data from trusted data sources in that situation would reflect a lower APTC than would be provided if the information from trusted data were used instead.

However, where electronic data sources reflect income under 100 percent FPL and a consumer attests to income between 100 percent FPL and 400 percent FPL, where the attested income exceeds the income reflected in trusted data sources by more than some reasonable threshold, we believe it would be reasonable to request additional documentation to protect against overpayment of APTC, since the consumer's attested income could make him or her eligible for APTC that would not be available using income data from electronic data sources. Accordingly, we proposed to add new paragraphs (c)(3)(iii)(D) and (E), and to modify paragraphs (c)(3)(vi)(C), (D), (F), and (G), to specify that the Exchange will follow the procedures in § 155.315(f)(1) through (4) to create an annual income data matching issue for consumers if: (1) The consumer attested to projected annual income between 100 percent and 400 percent of the FPL; (2) the Exchange has data from IRS and SSA that indicates income is below 100 percent FPL; (3) the Exchange has not assessed or determined the consumer to have income within the Medicaid or CHIP eligibility standard; and (4) the consumer's attested projected annual income exceeds the income reflected in the data available from electronic data sources by a reasonable threshold established by the Exchange and approved by HHS. We proposed that a reasonable threshold must not be less than 10 percent, and can also include a threshold dollar amount. In accordance with the existing process in § 155.315(f)(1) through (4), if the applicant fails to provide documentation verifying their income attestation, the Exchange would redetermine the applicant's eligibility for APTC and CSRs based on available IRS and SSA data, which under this proposal would typically result in discontinuing APTC and CSR as required in paragraph (c)(3)(vi)(G). The adjustment and notification process would work in a manner consistent with other inconsistency adjustments laid out in paragraph (c)(3)(vi)(F).

We proposed to allow the Exchange to set the threshold for setting a data matching issue similar to § 155.320(c)(3)(vi). We proposed that a reasonable threshold should take into account that consumers with incomes near 100 percent FPL have a smaller margin for error in dollar terms. Therefore, a reasonable threshold might also include a fixed dollar amount in addition to a percentage threshold.

We are finalizing this policy as proposed, with two changes. First, after considering the intended purpose of this new program integrity measure, we have decided to add additional regulatory language to § 155.320(c)(3)(iii)(D) that exempts from this additional verification check non-citizen applicants who are lawfully present and ineligible for Medicaid by reason of immigration status.[46] These applicants do not have the same incentive to inflate their reported household income to qualify for APTC, since they are also able to qualify for APTC with a household income under 100 percent FPL. Additionally, if these applicants inflate their income, they will receive less APTC than they are eligible for, and, therefore, performing the additional verification check is not necessary to prevent overpayment of APTC. Second, we also removed the proposed regulatory language that clarified that non-citizens who attested to projected income under 100 percent FPL are not subject to this verification, because the policy only applies to consumers who attested to projected annual income between 100 percent and 400 percent of the FPL, and therefore would not apply to any applicant (either citizen or lawfully present non-citizen), making this clarifying language unnecessary.

At § 155.320(c)(3)(vi)(D), we proposed to make changes to provide consistency with changes finalized in the 2017 Payment Notice regarding the threshold for the generation of annual income data matching issues for decreases in annual household income. This proposed change would specify that the 10 percent threshold standard no longer applies to cases when a tax filer's attested projected income is less than all data sources, or when no electronic data sources are available. Instead, an Exchange would use the reasonable threshold established in accordance with § 155.320(c)(3)(vi). We are finalizing this change as proposed.

In the proposed rule, we also noted our interest in providing further guidance on the appropriate thresholds for the generation of data matching issues generally. We intend to reconsider and provide further guidance

[46] FFEs generally verify citizenship/immigration status prior to verifying income. If an applicant's immigration status has not been verified when the income verification would occur, they would not be exempted from this additional verification check.

on these thresholds in the near future, and in anticipation of that effort, we sought comment on the appropriate thresholds to use at various income levels and in various circumstances. In particular, we welcomed data and evidence on this issue.

We intend to address this issue as part of broader rulemaking and guidance on a number of related program integrity issues, including further examination of our processes for denying eligibility for subsidies for individuals who have failed to reconcile APTC on their Federal income tax return, Exchange processes for matching enrollment data with Medicare and Medicaid in order to address consumers who may be enrolled in duplicative coverage, and our rules around recalculation of eligibility for APTC following a mid-year change in eligibility. In anticipation of these actions, we sought comment generally on these and other program integrity topics.

Comment: Several SBEs expressed concerns over the cost and time needed to implement the change in their IT systems to accommodate the proposed new verification process. They also stated that State Exchanges should have the flexibility to not conduct this verification. One commented that there is no incentive for applicants to inflate their income in a State that expanded Medicaid.

Response: HHS understands that Exchanges may need additional time to implement this proposal in order to update their information technology systems to incorporate new logic. However, we believe this is a critical program integrity measure. This process is primarily intended as a program integrity safeguard with respect to States that did not expand Medicaid. However the verification check could also help identify some applicants who inaccurately attested to too high an income amount and were therefore inaccurately determined or assessed not to be eligible for Medicaid. This check could help applicants identify potential eligibility through their State Medicaid program and encourage them to disenroll from their Exchange plan.

Comment: Many commenters were concerned that this new verification process would disadvantage households with lower household incomes, since these households often have income amounts that fluctuate more regularly and by a larger percentage margin than higher income households. Additionally, many commenters expressed concern that low-income consumers have difficulty in providing documentation to resolve their annual income data matching issues and that this proposal would exacerbate that problem. Commenters also suggested that HHS should more strongly consider providing notice to applicants that they should update their application with any income changes, rather than creating annual income data matching issues for this population.

Response: We recognize that households with lower income might experience higher relative levels of variance in their income from year-to-year. This policy recognizes the need to have a reasonable threshold for income discrepancies to allow for normal variations in income, which may include a dollar threshold amount. HHS believes that the alternate verification process has improved significantly since the program has launched. The calculator used by HHS to calculate income submitted by applicants has been specifically modified to handle instances where income fluctuates, or is seasonal in nature. We released a consumer guide to households to help them provide the correct documentation to verify their income in the event of an inconsistency. We also released a worksheet for households to help them verify their attested income amount. HHS supports encouraging applicants to continue to update their income throughout the year, as needed, through notices and other appropriate consumer outreach and educational materials. We are also exploring strategies to promote more timely and accurate reporting of changes in circumstances by consumers.

Comment: Several commenters expressed concern that HHS did not provide evidence or data that this issue was sufficiently problematic to require a change in the regulation.

Response: HHS acknowledges that it does not have firm data on the number of applicants that might be inflating their income to gain APTC, but believes that it is reasonable to design an appropriate program integrity check, particularly when incentives may exist for applicants to do so.

Comment: Commenters also suggested that instead of generating annual income data matching issues for this population, HHS should instead closely assess the eligibility for loss of MEC special enrollment periods involving the loss of Medicaid.

Response: HHS currently monitors and verifies eligibility for special enrollment periods due to loss of MEC, including the loss of eligibility for Medicaid/CHIP.

Comment: Several commenters expressed concern that applicants who could not successfully verify their income in States that have not expanded Medicaid would be left with no practical ability to purchase health insurance.

Response: HHS understands the concern regarding these consumers and believes the alternate verification process will be able to verify income information for applicants who accurately reported their income information. Applicants who inflate their income to gain access to APTC would not be able to produce documentation required to verify their income attestation, which would properly result in the inconsistency process under the proposed policy determining these applicants ineligible for APTC. This proposal is designed to provide a program integrity check that helps protect taxpayers from the overpayment of APTC.

Comment: One commenter stated that the proposal would not result in the Treasury recouping excess APTC paid for applicants who inflated their income to gain access to APTC because applicants with household income under 100 percent FPL are exempted from repaying APTC through the reconciliation process at tax time under current regulations.

Response: We view this policy as a critical program integrity measure, notwithstanding any liability that the tax filer may have when filing income taxes and reconciling APTC paid during the inconsistency period. As observed by the U.S. Government Accountability Office, without proper procedures for verifying incomes and family sizes, the risk of providing APTC on behalf of individuals who do not meet the minimum income eligibility requirements—including those who may purposefully misstate their incomes in order to gain access for APTC—is increased.[47] Particularly to the extent funds paid for APTC cannot be recouped through the tax reconciliation process, it is important to ensure these funds are not paid out inappropriately in the first instance.

Comment: One commenter suggested that the proposed policy could result in increased churn between Medicaid and coverage through the Exchange for

[47] U.S. Government Accountability Office, Improper Payments: Improvements Needed in CMS and IRS Controls over Health Insurance Premium Tax Credit (July 2017), available at *https://www.gao.gov/assets/690/685777.pdf.* See, also Office of Inspector General, U.S. Department of Health and Human Services, Not All of the Federally Facilitated Marketplace's Internal Controls Were Effective in Ensuring That Individuals Were Properly Determined Eligible for Qualified Health Plans and Insurance Affordability Programs (August 2015), available at *https://oig.hhs.gov/oas/reports/region9/91401011.pdf* (concluding that HHS should improve its processes for verifying income eligibility for insurance affordability programs).

consumers whose household income fluctuates near the 100 percent FPL level if they are unable to verify their income for APTC eligibility. The commenter was concerned that in States that expanded Medicaid, the applicants that lost their APTC would not necessarily know that their income may make them eligible for Medicaid.

Response: HHS acknowledges this concern and will explore ways to provide helpful information in any notice provided to these applicants that lose APTC because of their inability to verify their income and may be eligible for Medicaid.

We are finalizing the changes as proposed.

ii. Verification of Eligibility for Employer Sponsored Coverage (§ 155.320(d))

An employee, or a member of the employee's family, who is eligible to enroll in qualifying coverage in an eligible employer-sponsored plan is not eligible for the PTC unless the plan's coverage for the employee is either unaffordable, as defined in section 36B(c)(2)(C)(i)(II) of the Code, or does not provide minimum value, as defined in section 36B(c)(2)(C)(ii) of the Code. An employee (or member of the employee's family) also is not eligible if he or she actually enrolls in the employer-sponsored plan, even if the plan is not affordable or fails to provide minimum value.

When an individual submits a request for an eligibility determination for insurance affordability programs, including as part of the eligibility verification process for APTC and CSRs, § 155.320(d) requires the Exchange to verify whether the applicant reasonably expects to be enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested. Paragraph (d)(2) of § 155.320 describes the data sources an Exchange must use to perform verification. Paragraph (d)(2)(i) requires an Exchange to obtain data from any electronic data sources that are available to the Exchange and which have been approved by HHS based on evidence showing that such data sources are sufficiently current, accurate, and minimize administrative burden. Paragraph (d)(2)(ii) requires that the Exchange also obtain available data based on Federal employment through HHS, and paragraph (d)(2)(iii) requires the Exchange to obtain available data from the SHOP that corresponds to the State in which the Exchange is operating. Under § 155.320(d)(4), if an Exchange is unable to fulfill the requirement to connect to the data sources set forth in (d)(2), the Exchange is required to conduct sampling as described under paragraph (d)(4)(i), or—for benefit years 2016 and 2017—it may conduct an HHS-approved alternative process instead of sampling, as provided under paragraph (d)(4)(ii).

We proposed to amend § 155.320(d)(4) to allow an Exchange to conduct an HHS-approved alternative process instead of sampling, as provided under paragraph (d)(4)(ii), for benefit years through 2019. When we introduced this option for benefit years 2016 and 2017, we received comments that encouraged us to make this option permanent. However, at the time we stated that we believed the alternative process should be used as an interim measure to gather information about the verification process as Exchanges improve their long-term verification programs.[48] When we first introduced this option, we also stated that we believed the temporary option would provide Exchanges with needed flexibility as verification processes are refined and employer databases compiled, to improve long-term verification programs. We noted in the proposed rule that while Exchanges have since gained greater access to data and explored approaches to sampling, challenges remain. To reduce regulatory burdens on Exchanges while they address remaining hurdles to developing a long-term approach to verification, we stated we believe the option to use an alternative process instead of sampling should be extended through plan year 2019.

After the option to use an alternate process for benefit years 2016 or 2017 was finalized, HHS investigated the feasibility of connecting to a comprehensive database of information on employer-sponsored coverage that could be used by all Exchanges to fulfill verification requirements under § 155.320(d)(2)(i). Such a database would be most useful and cost-effective if it contained information on employer-sponsored coverage from as many non-Federal and non-SHOP employers as possible. We found that a comprehensive database does not currently exist and building such a database would be a resource-intensive endeavor. In addition, employers are not required to provide information to Exchanges or HHS regarding the coverage they offer, potentially limiting the completeness of such a database.

Because of the current challenges associated with building an HHS-approved database that is sufficiently complete and accurate to satisfy requirements under paragraph (d)(2)(i), we stated we anticipate many Exchanges will fulfill verification requirements using an alternate process, as described under paragraph (d)(4). In recognition of the challenges that Exchanges may encounter with conducting sampling, as explained below, we proposed to extend the option for Exchanges to conduct an alternative process to sampling through benefit year 2019. Our hope is that Exchanges can continue to compile databases sufficient to meet verification requirements under paragraph (d)(2) and to continue to refine their approaches to sampling to meet verification requirements under paragraph (d)(4)(i).

In accordance with the requirement at paragraph (d)(4) to pursue an alternate process, the FFE conducted a pilot study that incorporated many components of sampling. The pilot was intended to assess sampling's value protecting the integrity of the attestation process regarding applicant access to and enrollment in employer-sponsored coverage. As part of this sampling pilot, employers for a small sample of enrollees receiving APTC through the FFEs were contacted by telephone, based on the employer contact information applicants provided on their Exchange applications, and asked whether specified employees were also enrolled in a qualifying employer-sponsored plan or were offered qualifying coverage in an employer-sponsored plan. Since the FFE does not have access to relevant data from employers across the 38 States for which the FFE operates Exchanges, this effort provided an attempt to collect information on each sampled employee by contacting employers' human resources personnel. The FFE found that this approach was not a cost-effective way for the FFE to fulfill verification requirements using an alternate process.

We acknowledged that sampling may be a more cost-effective option for SBEs compared to FFEs. For example, the FFE operates Exchanges for 38 States, and the volume of employers that the FFE encompasses may inherently present challenges in relying on sampling results that States may not face. Some States may collect and have access to data from employers that make verifying consumers' attestations more efficient and reliable, or may have existing channels through which they can communicate with in-State employers. Therefore, we proposed to maintain the option to use sampling as an alternate method of verification under paragraph (d)(4) to allow SBEs maximum

[48] 81 FR 12203, 12269 (March 8, 2016).

flexibility. We stated that we expect that the proposed change to paragraph (d)(4) to allow Exchanges to continue to use an HHS-approved alternative process to sampling through plan year 2019 will provide Exchanges with important flexibility to conduct the most efficient, reliable alternate method of verification as Exchanges refine their approaches to conducting sampling over time, and until data sources exist that provide an effective way to verify consumers' enrollment in or access to qualifying employer-sponsored coverage. If SBEs use an alternative process to sampling to conduct verification under paragraph (d)(4)(ii), the process must be approved by HHS. To be approved by HHS, we expect an Exchange to develop an alternate process that provides insight into whether employees provide accurate information or the Exchange effectively verifies information about enrollment in and eligibility for qualifying coverage in an eligible employer-sponsored plan.[49] This requires Exchanges to conduct reliable and sufficient verification, while giving them the flexibility to find the most efficient ways of doing so for their Exchange.

We noted that to the extent an Exchange believes an alternate process to verification through data sources or methods other than those described under paragraph (d) may result in a more efficient or comprehensive verification procedure, the Exchange may also, in accordance with §§ 155.315(h) and 155.320(a)(2), request HHS approval for use of an alternate process for verifying enrollment in and access to employer-sponsored coverage. We noted that HHS received support for providing flexibility for the use of alternate data sources by Exchanges in comments to the Request for Information. For example, we received comments indicating that, for some Exchanges, due to the limited number of Federal employees in their State, connecting to the database containing data on Federal employment provides little utility in Exchange verification of applicants' eligibility for employer-sponsored coverage. One commenter encouraged HHS to consider removing the regulatory requirement to connect to this database for purposes of employer-sponsored coverage verification. We have also received feedback from some Exchanges noting challenges and limitations connecting to a SHOP database. These Exchanges noted that, given the limited enrollment in SHOP in many States and that many States do not have a SHOP database with which to connect, requiring verification through SHOP imposes a technical and financial challenge for States that may not be the most efficient and cost-effective way to perform verification.

Additionally, we sought information and suggestions on ways to improve verification of whether an applicant reasonably expects to be enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested.

We are finalizing this policy as proposed.

Comment: All commenters supported the proposal to amend § 155.320(d)(4) to allow an Exchange to conduct an HHS-approved alternative process instead of sampling, as provided under paragraph (d)(4)(ii), for benefit years through 2019. Most commenters noted the continued need to perform verification through an alternate process under paragraph (d)(4), and supported the flexibility to perform alternative methods of verification to sampling under paragraph (d)(4)(ii).

Response: We acknowledge the continuing need Exchanges may have to use an alternate verification process and the flexibility to perform an alternative verification procedure to sampling. We are finalizing this provision as proposed.

Comment: Most commenters indicated that challenges remain in performing verification through some or all of the databases described under paragraph (d)(2). One commenter questioned the value of verifying based on Federal employment data and through data based on the State's SHOP Exchange due to the low number of applicants offered eligible coverage from those sources in the relevant State. Several commenters supported the flexibility provided under § 155.315(h) for Exchanges to request HHS approval to perform verification through data sources or methods other than those specified in paragraph (d) where an Exchange believes alternate data sources or methods may result in a more efficient verification procedure for that Exchange.

Response: We agree that challenges remain to performing verification through databases described under paragraph (d)(2), and that an Exchange may believe verification through alternate data sources would be a more appropriate method of verification for their Exchange. While we believe that verification through databases described under paragraph (d)(2) remains a viable option for some Exchanges, we continue to provide Exchanges the flexibility afforded under § 155.315(h), and support Exchanges in considering this option for verification.

c. Eligibility Redetermination During a Benefit Year (§ 155.330)

We sought comment on ways to better encourage enrollees to report changes in circumstance occurring during the benefit year that may affect their eligibility for Exchange coverage or for APTC or CSRs. The FFEs currently conduct proactive outreach to enrollees through a variety of means, including emails, phone calls, and paper mail, to encourage them to return to the Exchange to update their information throughout the benefit year and during key Exchange operational efforts, such as open enrollment. The FFEs also periodically provide general information and reminders to enrollees. However, many changes in circumstance, such as changes in household income or size, remain unknown by the Exchanges until reported by the enrollee.

We are interested in hearing from stakeholders about ways to increase enrollee reporting of individual changes in circumstance within 30 days of the change in order to ensure compliance with § 155.330(b). Increasing such reporting would benefit enrollees by ensuring that they continue to be enrolled based on their current eligibility for financial assistance, and would improve program integrity.

Comment: Commenters supported finding ways to better encourage Exchange enrollees to report changes in circumstance during the benefit year so that they receive updated eligibility determinations, including with respect to any APTC they are receiving. Commenters acknowledged the benefit of timely updates to an enrollee's household income or family size as a way to help minimize any large APTC reconciliation payments due to the Federal government upon filing a Federal income tax return. Commenters also acknowledged the benefit to the program integrity of the Exchanges, so that they may continue to have updated and accurate enrollee information, as well as the benefit to the Federal government to minimize the amount of financial assistance being paid on behalf of enrollees who are not eligible (or are eligible for a lesser amount).

Commenters recommended increasing Exchange outreach efforts, through mail, email, and social media networks, to periodically remind consumers to report any life changes that may have occurred. One commenter recommended that Exchanges use more distinct envelopes when an enrollee action is required to improve the rate at

[49] 81 FR 94058, 94125 (December 22, 2016).

which these mailings are recognized, read, and acted upon. Commenters acknowledged the benefit of personal interactions as a way to encourage consumer behavior and recommended that Exchanges engage Navigators who have personal relationships with many Exchange enrollees to keep in contact with the enrollees throughout the year and remind them that they should timely report changes in circumstance to the Exchange.

Commenters recommended that Exchanges make it easier for enrollees to report changes in circumstance online. One State Exchange stated they have information about reporting changes in circumstance on the main page of their Exchange website outside of open enrollment, and that enrollees are asked about whether they need to report a change either over the phone if they call the Exchange call center, or online upon logging into their Exchange accounts.

Response: We appreciate comments received on this topic and will take them into consideration for FFE operations and possibly in future rulemaking.

d. Annual Eligibility Redetermination (§ 155.335)

We are considering the possibility of amending the length of time that individuals may authorize the Exchanges to obtain the updated tax return information for enrollees as described in § 155.335(k)(2). Currently, the Exchanges may obtain updated tax return information for a period of no more than 5 years based on a single authorization.

We sought comment on whether 5 years is an appropriate duration for this type of an authorization, or whether a shorter time period should be considered. In particular, we are contemplating whether shortening this authorization period would improve Exchange program integrity by helping to ensure that the enrollee's application at the time of re-enrollment accurately reflects his or her data collection preferences, that all sources of income that may affect his or her eligibility for APTC and cost-sharing reductions are listed on the application, and that individuals update their applications on a more regular basis to reflect other changes in circumstances that affect eligibility (such as changes in employment or marital status).

Comment: Many commenters opposed changing the length of time that individuals may authorize Exchanges to obtain their updated tax information. Many commenters agreed that 5 years is the appropriate length of time for this type of authorization, and that this period accurately balances the Exchanges' need for updated information with the consumer burden of actively authorizing Exchanges to access this information. One commenter recommended that we consider extending the authorization period past 5 years, and another recommended that Exchanges be able to access this information indefinitely. In addition, several commenters questioned how shortening this authorization window would improve Exchange program integrity.

Response: We appreciate the comments and will take them into consideration in future rulemaking.

5. Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

a. Special Enrollment Periods (§ 155.420)

i. Plan Options Under Select Special Enrollment Periods

For many special enrollment periods, a dependent of an Exchange enrollee may newly enroll in Exchange coverage or switch Exchange plans when the dependent or another qualified individual on the Exchange application qualifies for a special enrollment period. Even though dependents may access special enrollment periods based on different qualifying events, when they qualify for a special enrollment period to newly enroll in Exchange coverage, regardless of whether it is a special enrollment period due to gaining or becoming a dependent or due to a loss of minimum essential coverage, we believe that they should be treated alike. Section 155.420(a)(4) defines the coverage changes Exchange enrollees may make when they or their dependents qualify for special enrollment periods. We proposed to modify how paragraph (a)(4)(iii) treats dependents to align more closely with paragraph (a)(4)(i) which addresses when an existing enrollee gains a new dependent. To do this, we proposed to modify paragraph (a)(4)(iii) to establish a distinction between how the rule treats existing enrollees who qualify for one of the relevant special enrollment periods themselves or when existing Exchange enrollees themselves and their dependent(s) qualify for one of the relevant special enrollment periods; and when only new dependents qualify for one of the relevant special enrollment periods and are enrolling in coverage with an existing Exchange enrollee. We proposed to establish this distinction by separating these situations into new paragraphs (a)(4)(iii)(A) and (a)(4)(iii)(B). We believe the latter situation is akin to when an enrollee adds a new dependent to their coverage, even though in this situation the dependent is qualifying for a different special enrollment period.

Proposed new paragraph (a)(4)(iii)(A) would address the coverage options available to current enrollees and dependents who qualify for a special enrollment period. As is current policy under paragraph (a)(4)(iii), paragraph (a)(4)(iii)(A) would continue to allow enrollees and their dependents who qualify for the special enrollment periods specified in paragraphs (d), other than those described in paragraphs (d)(2)(i), (d)(4), (d)(6)(i) or (ii) for becoming newly eligible for CSRs, (d)(8), (d)(9), and (d)(10) of this section, to use their special enrollment period to change to another QHP within the same level of coverage or one metal level higher or lower, if no such QHP is available, as outlined in § 156.140(b) of this subchapter.

Proposed new paragraph (a)(4)(iii)(B) would address the coverage options available when only a dependent who is not currently enrolled in Exchange coverage qualifies for a special enrollment period. We proposed to revise the policy for these qualified individuals to align with paragraph (a)(4)(i) of this section. We proposed that, if a new dependent qualifies for one of the special enrollment periods specified in paragraphs (d)(1), (d)(3), (d)(6)(iii), (d)(6)(iv), (d)(7), (d)(11), and (d)(13) of this section and an enrollee would like to add the dependent to his or her QHP at that time, the Exchange must allow the enrollee to add the dependent to his or her current QHP; or, if the plan's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and dependent to change to another QHP within the same level of coverage; or, if no such QHP is available, allow them to switch to a QHP one metal level lower or higher, as outlined in § 156.140(b) of this subchapter. Alternatively, the enrollee may enroll the dependent in a separate QHP at any metal level.

We believe that these modifications are needed in order to align the flexibilities available to enrollees and dependents when a dependent is newly enrolling in Exchange coverage during the benefit year due to qualifying for a special enrollment period. With this proposed change, regardless of the special enrollment period for which a dependent qualifies, an enrollee may either add the dependent to his or her existing QHP, as long as he or she continues to qualify for it, or enroll the new dependent in a separate QHP at any metal level.

In the event that both the enrollee and the new dependent qualify for special enrollment periods referenced in proposed paragraphs (a)(4)(iii)(A) and (a)(4)(iii)(B), respectively, and the enrollee wants to add this new dependent to his or her QHP, the Exchange would allow both the enrollee and dependent to switch to a new QHP at the same metal level, if available, as described in proposed paragraph (a)(4)(iii)(A).

We are finalizing this policy as proposed.

Comment: The majority of commenters supported the proposal to align plan options for a dependent of an Exchange enrollee who qualifies for a special enrollment period to newly enroll in Exchange coverage along with the existing Exchange enrollee, regardless of the special enrollment period the dependent qualifies for, thereby aligning the dependent policies in paragraphs (a)(4)(i) and (a)(4)(iii)(B). Commenters appreciated the simplification of plan option rules for enrollees who seek to newly enroll a dependent in Exchange coverage after that dependent has qualified for a special enrollment period, and stated that this simplification will benefit Exchange enrollees, as well as those providing enrollment assistance, such as Navigators, agents, and brokers, by making it easier for them to understand and explain the enrollee's enrollment options. In addition, some commenters supported aligning the plan option rules out of fairness, to ensure that all similarly situated dependents who are newly enrolling in Exchange coverage should have the same enrollment options available to them.

A few commenters supported this proposal, but also requested that changes to the plan option restrictions in paragraph (a)(4) be amended to give affected enrollees and dependents the option to enroll in a QHP at a lower level of coverage, alongside the option to enroll in either the same QHP or another QHP at the same level of coverage, as applicable. Commenters stated that this increased flexibility is especially necessary for situations where enrollees are gaining or become a new dependent, in accordance with paragraph (d)(2)(i) of this section, because changes in household composition, especially the addition of a new infant or child to a household, likely change a household's health care needs and what level of coverage is best suited to meet those needs. Other special enrollment periods included in paragraph (a)(4)(iii)(B), such as the special enrollment periods for loss of minimum essential coverage in paragraph (d)(1) of this section and for being determined ineligible for Medicaid or the Children's Health Insurance Program, may similarly change a household's health care needs if, for example, dependents had been previously enrolled in Medicaid or CHIP and are losing that coverage for the first time.

Several commenters expressed concern about the technical impact the proposed changes would have on State Exchanges, especially those States that had already been working toward implementing the plan option restrictions as finalized in the 2017 Market Stabilization Rule. States cautioned that finalizing this proposal would delay their ability to implement this policy and several States requested State flexibility with respect to this proposal.

Other commenters expressed opposition to this proposed change because it would further restrict plan options available to enrollees and dependents newly enrolling in QHP coverage. These commenters stated that imposing restrictions of individuals' choice of QHPs to enroll in after he or she qualifies for a special enrollment period contradicts the intent of special enrollment periods. One commenter stated that limiting plan options for enrollees or dependents upon qualifying for a special enrollment period is prohibited by the guaranteed issue provision of the PPACA statute. The guaranteed issue provision requires that issuers accept every individual in the State who applies for such coverage and, while issuers may restrict enrollment periods, they stated, restrictions on the type of plan the individual enrolls in is not permitted.

Response: We agree that there is a benefit to aligning the plan options available to enrollees who are adding a dependent newly enrolling in Exchange coverage through a special enrollment period. We appreciate commenters' concerns about the impact household changes may have on a family's health coverage needs, but believe that maintaining these restrictions is necessary in order to continue to avoid adverse selection. We continue to encourage enrollees to explore all available QHPs during open enrollment, and to change plans if another QHP better meets their or their family's needs.

We understand that the proposed changes may delay State Exchanges' ability to implement the plan option restrictions, especially in those States where this proposal will require a change to Exchange system functionality, and, therefore, we believe it is appropriate for States to take additional time, as needed, in order to comply with this change.

Lastly, as we noted in the 2017 Market Stabilization Rule, we considered the concerns regarding conflicts of this policy with the statute, but believe that limiting enrollees' ability to change QHPs or metal levels is consistent with the requirements in section 1311(c)(6)(C) of the PPACA directing the Secretary to require Exchanges to establish special enrollment periods as specified in section 9801 of the Code and under circumstances similar to such periods under Part D of title XVIII of the Act, as well as the Secretary's authority under section 2702(b)(3) of the PHS Act to promulgate regulations for the individual market with respect to special enrollment periods for qualifying events under section 603 of the Employee Retirement Income Security Act of 1974. Given that the PPACA itself called for one annual open enrollment period and additional enrollment opportunities only in the case of special circumstances, we believe it is reasonable to interpret the special enrollment period and guaranteed issue provisions of the PPACA in this manner.

We proposed to exclude the special enrollment period in paragraph (d)(12) for material plan or benefit display errors from paragraph (a)(4)(iii). This is because we understand that certain material plan or benefit display errors may impact an enrollees' decision to enroll in a level of coverage, in addition to his or her decision to enroll in a specific QHP. Therefore, we believe that, if an enrollee qualifies for the special enrollment period because of a material plan or benefit display error, he or she should be allowed to switch to a different QHP at any metal level that better meets his or her needs.

We are finalizing the policy as proposed.

Comment: Commenters supported the proposal to exempt from the plan option restrictions in paragraph (a)(4)(iii) the special enrollment period in paragraph (d)(12) for when a qualified individual, enrollee, or his or her dependent adequately demonstrates to the Exchange that a material error related to plan benefits, service area, or premium influenced the qualified individual's or enrollee's decision to purchase a QHP through the Exchange. Such a material plan error may have impacted not only the specific QHP an individual enrolled in, but also the level of coverage the individual decided to purchase. One commenter requested that we provide additional guidance regarding the types

of errors that we would consider material for purposes of being excluded from the plan option restrictions in paragraph (a)(4)(iii).

Response: We are finalizing this policy as proposed. We also clarify that, while we are finalizing an amendment to exempt this special enrollment period from the plan option restrictions in paragraph (a)(4)(iii), we are not amending the criteria for qualifying for the special enrollment period in paragraph (d)(12), which is intended for when an enrollee adequately demonstrates to the Exchange that a material error related to plan benefits, service area, or premium influenced the qualified individual's or enrollee's decision to purchase a QHP through the Exchange and refer the commenter to the preamble discussion of the 2018 Payment Notice where we discuss this special enrollment period.

ii. Exception to Prior Coverage Requirement for Qualified Individuals Who Have Lived in Service Areas Where No QHP Is Offered Through an Exchange

HHS recently added a prior coverage requirement to the special enrollment period for gaining access to new QHPs as a result of a permanent move, described in § 155.420(d)(7), and the special enrollment period for gaining or becoming a dependent through marriage, described in § 155.420(d)(2)(i). Section 155.420(a)(5) specifies how a qualified individual can satisfy the prior coverage requirement. Qualified individuals can demonstrate that they had minimum essential coverage as described in 26 CFR 1.5000A–1(b) for 1 or more days during the 60 days preceding the date of the qualifying event; lived in a foreign country or in a United States territory for 1 or more days during the 60 days preceding the date of the qualifying event; or are an Indian, as defined by section 4 of the Indian Health Care Improvement Act. This prior coverage requirement encourages individuals to maintain coverage throughout the year.

However, we recognize that individuals living in a service area where no Exchange QHPs are offered may not be able to obtain affordable coverage. We believe that individuals in this situation should not later be prevented from enrolling in coverage through a special enrollment period that requires prior coverage when they were previously unable to enroll in Exchange coverage because it was unavailable or inaccessible. Therefore, we proposed to amend paragraph (a)(5) to exempt qualified individuals from the prior coverage requirement if, for at least 1 of the 60 days prior to the date of their qualifying event, they lived in a service area where there were no QHPs offered through an Exchange. Absent this change, qualified individuals who have lived for part of the benefit year in a location where no QHPs were offered through an Exchange, and, therefore, may have been unable to enroll in minimum essential coverage, would be prevented from subsequently qualifying for a special enrollment period due to a permanent move or marriage.

Additionally, we noted that the proposed amendment to paragraph (a)(5) would apply, along with the rest of the paragraph, to the individual market outside of the Exchange through the cross-reference to § 155.420(d) in § 147.104(b)(2). In this context, health insurance issuers offering coverage outside an Exchange would not be able to require qualified individuals to demonstrate prior coverage if they lived for at least 1 of the 60 days prior to their qualifying event in a service area where there were no QHPs offered through an Exchange.

We are finalizing the policy as proposed, except that we are amending the regulatory text to ensure the exception applies to individuals who lived in a service area where no QHPs were offered through an Exchange during their most recent Exchange enrollment period, regardless of whether that enrollment period was an Exchange open enrollment period or a special enrollment period. This change will address situations where no QHPs were available to an individual during their enrollment window, but later became available in the individual's service area prior to his or her marriage or move.

Comment: Commenters supported the proposal to exempt qualified individuals from the prior coverage requirement if, for at least 1 of the 60 days prior to the date of their qualifying event, they lived in a service area where there were no QHPs offered through an Exchange. Several commenters added that HHS should continue to implement procedures currently in place to verify other aspects of the applicable special enrollment period qualifying event, such as a move, within the required 60-day window. Commenters also requested, if this exception to the prior coverage requirement becomes necessary, that HHS publish a list of service areas in which no QHPs are offered through an Exchange, in part to ensure that issuers can apply the exception accurately in the off-Exchange individual market.

One commenter raised the concern that our proposed criteria for the exception, in particular that a person only have lived for 1 of the 60 days prior to their qualifying event in a service area where there were no QHPs offered through an Exchange, was not stringent enough. This commenter suggested that such a brief residency requirement could lead individuals to move to an affected service area on a transitional basis in order to avoid the prior coverage requirement. To reduce the likelihood that individuals who did not qualify would be able to take advantage of this exception, the commenter recommended that we require individuals to have been residents in a service area without QHPs for the entire 60 day period prior to their qualifying event.

Response: We will consider publishing a list of service areas in which no QHPs are offered by the Exchange, so that this exception can be applied consistently and accurately off-Exchange. In addition, we may release additional guidance if a service area is left without QHP coverage and it becomes necessary to implement this exception.

We understand concerns that individuals may seek to fraudulently claim this exception in order to avoid the prior coverage requirement, and we remain committed to promoting continuity of coverage and ensuring that only eligible consumers may access coverage through special enrollment periods. However, we believe that this exception for individuals who have lived in a service area where no QHPs are offered by the Exchange for at least 1 of the 60 days before a qualifying event or during their most recent preceding enrollment period is important, because it takes into account the potential for a service area to temporarily be without a QHP, such as in the case of a temporary QHP suppression or mid-year QHP decertification, and the need to protect individuals who may be affected by this lack of availability. Additionally, we note the need to ensure that individuals are not prevented from accessing coverage through a special enrollment period mid-year because of having lived in a service area where no QHPs were offered through the Exchange during their most recent enrollment period (open enrollment or special enrollment period) when they could have otherwise enrolled in affordable coverage, even if during the 60 days before a subsequent qualifying event a QHP is available in their service area. Therefore, we are finalizing this exception to the prior coverage requirement that currently applies to certain special enrollment periods to include consumers who lived

in a service area where no QHP was available through the Exchange during their most recent preceding enrollment period.

We also note that concerns that individuals will fraudulently claim eligibility for an exception to the prior coverage requirement are addressed in part because the FFE will continue to require document-based verification of the individual's eligibility for the special enrollment period and, in order to qualify for the special enrollment period due to a permanent move, individuals will continue to be required to meet the residency requirements for their new and former addresses, in accordance with § 155.305(a)(3) and as explained in the January 2016 *FAQs on the Marketplace Residency Requirement and the Special Enrollment Period due to a Permanent Move.*[50] Finally, we anticipate that this exception will be granted extremely rarely, which minimizes the risk that it will be used inappropriately.

iii. Effective Date Options for Special Enrollment Periods Relating To Gaining or Becoming a Dependent

Paragraph (b)(2)(i) of § 155.420 requires Exchanges to provide individuals who qualify for a special enrollment period due to gaining or becoming a dependent through birth, adoption, placement for adoption, or placement in foster care, as described in paragraph (d)(2)(i), with a retroactive coverage effective date back to the date of the qualifying event. It also gives Exchanges the option to allow these consumers to elect an effective date of the first of the month following the date of the event or following regular coverage effective dates, in accordance with paragraph (b)(1) of this section. Paragraph (b)(2)(v) addresses coverage effective date options for special enrollment periods related to gaining or becoming a dependent due to a child support or other court order, as also described in paragraph (d)(2)(i). It requires Exchanges to ensure that coverage takes effect on the date of the court order, and it permits Exchanges to allow qualified individuals to elect an effective date based on paragraph (b)(1). However, it does not provide Exchanges with the option to allow qualified individuals to elect that their coverage begin the first of the month following the date of the event.

We proposed to remove paragraph (b)(2)(v) of this section and to revise paragraph (b)(2)(i) to include the special enrollment period for a court order and redesignate current paragraph (b)(2)(vi) as paragraph (b)(2)(v). These revisions would align the coverage effective dates for all special enrollment periods based on gaining or becoming a dependent, with the exception of gaining or becoming a dependent through marriage. Aligning coverage effective date options ensures that Exchanges provide qualified individuals in similar situations with the same flexibility with regard to coverage effective dates.

We also proposed to modify paragraph (b)(2)(i) so that, in addition to requiring an Exchange to ensure that coverage is effective retroactive to the date of the qualifying event, it may permit the qualified individual or enrollee to elect a coverage effective date of the first of the month following plan selection, rather than the first of the month following the qualifying event, as currently written, or following regular coverage effective dates, in accordance with paragraph (b)(1) of this section. This amendment would streamline Exchange operations and align this coverage effective date option with the accelerated prospective coverage effective date rule as it applies to other special enrollment periods, including the special enrollment period for gaining or becoming a dependent through marriage, as described in (b)(2)(ii) of this section.

Therefore, individuals who qualify for a special enrollment period due to gaining or becoming a dependent through birth, adoption, placement for adoption, or placement in foster care, or through a child support or other court order, will be able to elect from the same alternate coverage effective date options, if offered by their Exchange.

We are finalizing this policy as proposed.

Comment: Commenters supported the proposal to align the coverage effective date options for those who gain or become a dependent through birth, adoption, or foster care placement with those who gain or become a dependent through a child support or other court order. Commenters agreed that aligning special enrollment period coverage effective date options for most situations where individuals are gaining or becoming a dependent would result in a simpler rule and more intuitive operational processes, both reducing administrative burden on issuers and on agents and brokers and helping individuals better understand their coverage effective date options. One commenter opposed this proposal due to concerns that it would reduce State flexibility, could increase burden on Exchanges due to costs associated with updating their systems to reflect new effective date options in States that offer this optional alternate coverage effective date option to consumers, and limit individuals' access to retroactive coverage options.

Response: We agree that these changes will promote the goals of providing the same alternate coverage effective date options to consumers who qualify for a special enrollment period due to gaining or becoming a dependent through a birth, adoption, foster care placement, or court order, and of streamlining Exchange operations by revising the ''first of the month'' coverage effective date option so that it can be operationalized in the same way for all special enrollment periods for which it is an option. We note that this proposal does not remove or alter the requirement at § 155.420(b)(2) that Exchanges ensure that coverage is effective retroactive to the date of the qualifying event for consumers who qualify for a special enrollment period due to gaining or becoming a dependent through a birth, adoption, foster care placement, or court order.

We acknowledge that allowing Exchanges to permit individuals to elect that their coverage take effect on the first of the month following plan selection instead of on the first of the month after the date of their qualifying event will mean that consumers only have one option for their coverage to take effect retroactively—back to the date of their qualifying event—whereas prior to the change, they could request that coverage take effect retroactive to the first of the month after their qualifying event if their Exchange allowed this option. However, we also note that the proposed change adds an accelerated prospective option that is not currently available to these consumers.

Additionally, we believe that, while some Exchanges may need to make system updates based on this change, they will have the flexibility that they need in order to manage the potential impact because Exchanges are not required to offer these alternate coverage effective date options and may delay implementation if necessary. Finally, the alignment of this effective date option with the ''first of the month'' effective date that also applies to other types of special enrollment periods (in particular the special enrollment period due to gaining or becoming a dependent through a marriage), will also likely generate efficiencies for Exchanges in the long term.

[50] Available at *https://www.regtap.info/uploads/library/ENR_FAQ_ResidencyPermanentMove_SEP_5CR_011916.pdf.*

iv. Loss of Coverage Special Enrollment Period (§ 155.420(d)(1)(iii))

Section 155.420(d)(1) establishes a special enrollment period for qualified individuals who lose certain types of coverage, including minimum essential coverage. As described in paragraph (d)(1)(iii), qualified individuals who lose certain types of Medicaid pregnancy-related coverage not considered minimum essential coverage may also qualify for this special enrollment period. This is to ensure that women losing eligibility for coverage of pregnancy-related services that often meet their primary and specialty health care needs are not left without the option to enroll in a QHP through an Exchange after they lose access to those services.

We proposed to revise paragraph (d)(1)(iii) to include women who lose access to health care services that they were receiving through CHIP coverage for their unborn child. While CHIP coverage for unborn children, provided based on the definition of a child described in 42 CFR 457.10, is considered minimum essential coverage for the unborn child, it is not considered minimum essential coverage for the pregnant woman. Nonetheless, these pregnant women may receive a set of health services comparable to those available to women enrolled in Medicaid pregnancy-related coverage. For this reason, pregnant women who have received prenatal care as part of CHIP coverage for their unborn child may apply and be determined eligible for a hardship exemption from the FFEs so that they are not required to also maintain minimum essential coverage during that time.

The proposed revision to paragraph (d)(1)(iii) would provide a pathway to coverage for new mothers who lose access to health care services provided through unborn child CHIP coverage following the birth of their child, and who are otherwise eligible to enroll in a QHP through the Exchange. Under paragraph (c)(2) of this section, these qualified individuals would have up to 60 days before or after the loss of access to CHIP unborn child coverage to qualify for the loss of coverage special enrollment period and enroll in a QHP. If they select a plan prior to their loss of CHIP unborn child coverage, their Exchange coverage would begin as soon as the first day of the month following the loss of coverage. If they select a plan after the loss of CHIP unborn child coverage, their Exchange coverage would begin either the first of the following month or following regular, prospective coverage effective dates at the option of the Exchange, as provided under paragraph (b)(2)(iv). We believe that this revision is needed to ensure a pathway to coverage for women in the 17 States that offer unborn child CHIP coverage, so that they may maintain access to continuous coverage after the birth of their child.

We are finalizing this policy as proposed.

Comment: We received overwhelming support for this proposal; commenters did not raise any concerns, and noted that it would help streamline Exchange operations and ensure that women losing access to CHIP coverage for their unborn child are able to maintain continuous coverage.

Response: We are finalizing this provision as proposed.

iv. Technical Amendment (§ 155.420(d)(10)(i))

We proposed to make a technical amendment to update the cross reference to 26 CFR 1.36B–2T in § 155.420(d)(10)(i), regarding the special enrollment period for victims of domestic abuse or spousal abandonment. The temporary regulation under section 36B of the Code originally cited has now been finalized without change to the definition cited in this special enrollment period. This technical correction would not alter the parameters of this special enrollment period.

Commenters supported this proposal; we are finalizing this change as proposed.

b. Effective Dates for Terminations (§ 155.430)

Section 155.430 specifies the termination dates for Exchange enrollees. Paragraph (d)(1)(i) of § 155.430 defines ''reasonable notice'' as at least 14 days before the requested effective date of termination. Paragraph (d)(2) sets forth three possible effective dates for enrollee-initiated terminations made in accordance with paragraph (b)(1): (1) The termination date specified by the enrollee, if the enrollee provides reasonable notice; (2) 14 days after the termination is requested by the enrollee, if the enrollee does not provide reasonable notice; or (3) on a date on or after the date on which the termination is requested by the enrollee, if the enrollee's QHP issuer agrees to effectuate termination in fewer than 14 days, and the enrollee requests an earlier termination effective date. Further, current paragraph (d)(2)(iv) sets the QHP termination effective date for enrollees newly eligible for Medicaid, CHIP, or the Basic Health Program (BHP) as the day before the individual is determined eligible for Medicaid, CHIP, or BHP.

We proposed to remove paragraphs (d)(1)(i) and (d)(2)(i) through (d)(2)(iii) to align the effective dates for all enrollee-initiated terminations on the date on which the termination is requested by the enrollee or on another prospective date selected by the enrollee. We also proposed removing existing paragraph (d)(2)(iv), which states that the QHP termination date for an enrollee newly determined eligible for Medicaid, CHIP or a BHP is the date before the Medicaid, CHIP, or BHP eligibility determination. We invited comment from Exchanges, issuers, and other stakeholders on any burdens these rule changes may impose, as well as whether we should make the changes at the option of the Exchange or the issuer.

We are not finalizing this policy as proposed. Rather, we are restructuring paragraph (d)(2) to improve its readability, and, in response to comments from Exchanges responding to our solicitation of comments, providing additional flexibility to allow Exchanges to retain the current policy or operate under the proposed policy.

Comment: Supporters of our proposal to eliminate the ''reasonable notice'' requirement referenced the more streamlined and straightforward approach to terminations for consumers and its ability to reduce duplicate or overlapping coverage when enrollees obtain other coverage. Many supporters cited challenges consumers face transitioning into Medicare and stated that being able to choose the date of their QHP termination would alleviate the need to reach out to the Exchange multiple times to ensure the proper termination date to avoid having dual coverage.

Response: We agree that allowing enrollees to terminate their coverage immediately or on a future date of their choosing will provide consumers with greater control over ending their QHP coverage and will help minimize or eliminate overlaps in coverage, for example, when aging into Medicare. Such flexibility will also allow Exchanges to send termination transactions to issuers that do not need subsequent adjustment, reducing the need for casework or direct consumer contact with issuers to request termination dates to effectuate in less than 14 days.

Comment: Some commenters requested that we provide flexibility in the implementation of this rule, citing technical and operational challenges with premium proration, in addition to the common consumer desire to terminate plans at the end of the month.

Response: We acknowledge that not all Exchanges have the same system capabilities, and are providing Exchanges flexibility to implement this change at their discretion.

Comment: Several commenters opposed the rule, stating that 14 days is a reasonable industry practice for issuers, while others expressed concerns that same-day terminations are not feasible for issuer processing, due to the timing of Exchange-sent 834 transactions. Some urged HHS to work with issuers to determine a more realistic timeframe—ranging from next-day to 5 days—and implement a default end-of-month termination effective date. One commenter discussed the importance of coordination between issuers and Exchanges to synchronize enrollment and termination effective dates to reduce adverse downstream effects on payment reconciliation processes.

Response: Issuers already process a significant number of same-day terminations when removing less than the whole enrollment group from QHP coverage, and they have reported no difficulties in doing so. While we expect the vast majority of enrollees will want their coverage to end at the end of month, this option for a more precise termination date is necessary for consumers because retroactive terminations are only available in very limited circumstances.

Comment: One commenter urged us to allow issuers to transmit 834 files to the Exchange with consumer-initiated terminations, stating that most consumers notify their issuers first when terminating coverage.

Response: We recognize that many enrollees reach out to their issuers to initiate terminations. However, terminations must be triggered through the Exchange so enrollees remaining on the application can receive an updated eligibility determination.

Comment: Supporters of the proposal to remove the current Medicaid/CHIP/BHP termination rule—which allows for retroactive QHP terminations based on new Medicaid/CHIP/BHP eligibility determinations—described the current rule as a source of confusion for issuers, States, Exchanges and consumers, and noted challenges coordinating with State Medicaid agencies, as well as the volume of complex casework the rule currently triggers. One commenter recommended that HHS permit retroactive QHP terminations if the Medicaid, CHIP or BHP determination was less than 30 days in the past because it is more difficult for plans to reverse claims after 30 days.

A few commenters encouraged flexibility to maintain existing policy and business operations, and others encouraged HHS to allow States to determine how the change would impact their populations, given their Medicaid eligibility processing times, as well as their ability to reach and inform consumers about their need to take action.

Response: We agree that the current Medicaid/CHIP/BHP rule causes unnecessary confusion, given that we do not provide QHP termination dates according to eligibility for other forms of coverage, such as Medicare or employer-sponsored coverage. We also recognize that eligibility determinations conducted through the State Medicaid agency, instead of the Exchange, can result in challenges coordinating effective dates through the State agency, the Exchange, and its issuers; and can result in consumer complaints and subsequent casework. We recognize issuer challenges with retroactive terminations and appreciate willingness to process limited retroactive terminations. However, because we recognize that Exchanges' coordination with their Medicaid and CHIP programs varies, we are providing Exchanges flexibility to implement this change at their discretion.

Comment: Most commenters who opposed the proposal to remove the Medicaid/CHIP/BHP rule cited adverse consumer impact, and were primarily concerned about placing the burden to terminate QHP coverage on the Medicaid/CHIP/BHP enrollee who may not understand the need to terminate. One commenter stated it was important for QHP enrollees to continue to be able to recoup premium payments made when in fact eligible for Medicaid due to Medicaid's 90-day retroactive eligibility rules. Others stated that the QHP should terminate automatically with Medicaid eligibility.

Response: We recognize there may be some consumer impacts with the implementation of this rule. We also recognize that the removal of this rule may limit enrollees' ability to retroactively terminate QHP coverage when it overlaps with Medicaid/CHIP/BHP coverage, which could result in consumers being unable to recoup premiums paid for periods when the enrollee was enrolled in QHP coverage through the Exchange and gains retroactive eligibility for Medicaid/CHIP/BHP. However, these types of retroactive terminations can lead to major challenges for consumers as Medicaid/CHIP/BHP providers may not cover claims reversed by the QHP—leading to unexpected out-of-pocket costs for consumers. Finally, we agree that automatic transition from QHP coverage to Medicaid/CHIP/BHP coverage without consumer intervention is a worthy goal, but we recognize that many Exchanges do not have real-time coordination with their Medicaid/CHIP/BHP agencies in order to do so.

Comment: A few commenters expressed concerns about possible downstream effects on eligibility for future QHP coverage from putting the full responsibility for QHP termination on the Medicaid/CHIP/BHP consumer. For example, if a consumer fails to terminate QHP coverage for which APTC are paid, he may stop paying premiums because he is enrolled in Medicaid and the issuer will terminate his coverage for nonpayment. At the end of the grace period, he will still owe premium for one month of coverage after the Medicaid determination.[51] Under certain circumstances set forth in the Market Stabilization final rule,[52] the QHP issuer could then attribute payments made toward subsequent enrollments to the premium amount owed, and deny enrollment in the new coverage for failure to pay the binder payment. In regions with only one issuer, this could leave consumers who rise above the Medicaid income threshold without access to coverage options.

Response: We acknowledge there may be downstream effects on eligibility for future QHP coverage due to non-payment of premiums for those who do not terminate their coverage timely and enter a grace period. The FFEs continue to make IT improvements and enhance consumer education and outreach with the purpose of making it easier and clearer for an individual to terminate QHP coverage in a timely manner.

6. Definitions (§ 155.500)

This section defines terms that are relevant to this subpart. We proposed to amend the definitions of ''Appeal request'' and ''Appeals entity'' by adding a cross reference to proposed section § 155.716(e)'' to align with other proposals discussed throughout the proposed rule, and finalized in this rule, regarding SHOP. We did not receive substantive comments specific to this proposal, and are finalizing as proposed.

[51] This grace period only applies to APTC recipients. Termination rules for non-payment of premium default to State law for non-financial assistance enrollees, for whom the last day of coverage is generally the last day of the month in good standing.

[52] 82 FR 18349–18353.

7. Eligibility Standards for Exemptions (§ 155.605)

a. Hardship Exemptions (§ 155.605(d))

Section 1311(d)(4)(H) of the PPACA and section 5000A(e)(5) of the Code allow individuals to seek an exemption from the individual shared responsibility provision due to a lack of affordable coverage based on an individual's projected income. Although tax reform legislation enacted in December 2017 reduces to $0 the individual shared responsibility payment for months beginning after December 31, 2018, individuals may still have a need to seek a hardship exemption for 2019 and future years due to a lack of affordable coverage based on projected income. For example, individuals may continue to seek a hardship exemption after 2018 to be eligible for catastrophic coverage.

Section 155.605(d)(2) establishes the circumstances under which an Exchange must determine an applicant eligible for an exemption due to lack of affordable coverage based on projected income. For determining whether affordable coverage is available, paragraph (d)(2) states that the Exchange should use the standards specified in section 5000A(e)(1) of the Code that, among other things, specify that the Exchange should use, for individuals not eligible for employer-sponsored coverage, the annual premium for the lowest-cost bronze plan available in the individual market through the Exchange in the State in the county in which the individual resides.

However, market instability has resulted in limited offerings of plans on the Exchanges in many regions, and there may be individuals who live in a county without a bronze plan. Under the current regulation, the Exchange would not be able to make a determination as to whether an individual not eligible for employer-sponsored coverage who lives in a rating area without a bronze plan is eligible for the exemption due to lack of affordable coverage based on projected income. We proposed to amend paragraph § 155.605(d)(2)(iv), to allow an Exchange to make a determination of lack of affordable coverage based on projected income for individuals not eligible for employer-sponsored coverage using the annual premium for the lowest cost Exchange metal level plan, excluding catastrophic plans, available in the individual market through the Exchange in the State in the county in which the individual resides if there is no bronze level plan sold through the Exchange in that county. Absent this proposed change, individuals may lack access to affordable coverage, but be unable to qualify for an exemption determination from the Exchange due to the Exchange's inability to calculate whether coverage is unaffordable due to the absence of a bronze plan in that county. Under the proposed amendment to § 155.605(d)(2), Exchanges would use the amount of the lowest cost Exchange metal level plan available to the individual when no bronze level plan is available.

Comment: All commenters supported the proposed change to use the lowest cost metal level plan when calculating whether a plan is affordable in the instances when no bronze plan is available. Commenters suggested that the regulatory text clarify that the determination of the lowest-cost plan is made at the county level rather than the rating area level, and that the determination of the ''lowest-cost Exchange plan'' on which to base eligibility for an exemption should be made without consideration of catastrophic plans. Some commenters supported the proposal, but asked that the exemption not be interpreted broadly so that the exemption would weaken the risk pool. One commenter recommended that HHS bring forward the effective date of the rule to plan year 2018.

Response: We are finalizing this policy, and are clarifying that eligibility for an exemption should be made at the county level and without consideration of catastrophic plans. We appreciate the concerns about the risk pool, but believe that this change is targeted specifically to handle the issue of when no bronze plans are available to the individual. This change will be effective on the effective date of this rule, which occurs during the 2018 plan year.

b. Required Contribution Percentage (§ 155.605(e)(3))

Under section 5000A of the Code, an individual must have minimum essential coverage for each month, qualify for an exemption, or make an individual shared responsibility payment. Under section 5000A(e)(1) of the Code, an individual is exempt if the amount that he or she would be required to pay for minimum essential coverage (the required contribution) exceeds a particular percentage (the required contribution percentage) of his or her actual household income for a taxable year. In addition, under § 155.605(d)(2), an individual is exempt if his or her required contribution exceeds the required contribution percentage of his or her projected household income for a year. Finally, under § 155.605(d)(2)(iv), certain employed individuals are exempt if, on an individual basis, the cost of self-only coverage is less than the required contribution percentage, but the aggregate cost of individual coverage through employers exceeds the required contribution percentage and no family coverage is available through an employer at a cost less than the required contribution percentage. Although tax reform legislation enacted in December 2017 reduces to $0 the individual shared responsibility payment for months beginning after December 31, 2018, individuals may continue to seek a hardship exemption based on the required contribution amount after 2018 to obtain catastrophic coverage. Further, the excess of the rate of premium growth over the rate of income growth also is used for determining the applicable percentage in section 36B(b)(3)(A) of the Code and the required contribution percentage in section 36B(c)(2)(C) of the Code. As such, we are continuing to finalize the excess of the rate of premium growth over the rate of income growth and the required contribution percentage for the 2019 benefit year below.

Section 5000A of the Code established the 2014 required contribution percentage at 8 percent. For plan years after 2014, section 5000A(e)(1)(D) of the Code and 26 CFR 1.5000A–3(e)(2)(ii) provide that the required contribution percentage is the percentage determined by the Secretary of HHS that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that period.

We established a methodology for determining the excess of the rate of premium growth over the rate of income growth for plan years after 2014 in the 2015 Market Standards Rule (79 FR 30302), and we stated that future adjustments would be published annually in the HHS notice of benefit and payment parameters.

Under the HHS methodology, the rate of premium growth over the rate of income growth for a particular calendar year is the quotient of (x) 1 plus the rate of premium growth between the preceding calendar year and 2013, carried out to ten significant digits, divided by (y) 1 plus the rate of income growth between the preceding calendar year and 2013, carried out to ten significant digits.[53]

[53] We also defined the required contribution percentage at § 155.600(a) to mean the product of 8 percent and the rate of premium growth over the rate of income growth for the calendar year,

Continued

As the measure of premium growth for a calendar year, we established in the 2015 Market Standards Rule that we would use the premium adjustment percentage. The premium adjustment percentage is based on projections of average per enrollee employer-sponsored insurance premiums from the National Health Expenditure Accounts (NHEA), which are calculated by the CMS Office of the Actuary.[54] (As discussed elsewhere in this preamble, we are finalizing the proposed 2019 premium adjustment percentage of 1.2516634051, (or an increase of about 25 percent over the period from 2013 to 2018). This reflects an increase of about 7.7 percent over the 2018 premium adjustment percentage (1.2516634051/1.1617303196).)

As the measure of income growth for a calendar year, we established in the 2017 Payment Notice that we would use per capita personal income (PI). Under the approach finalized in the 2017 Payment Notice, and using the NHEA data, the rate of income growth for 2019 is the percentage (if any) by which the most recent projection of per capita PI for the preceding calendar year ($53,729 for 2018) exceeds per capita PI for 2013 ($44,555), carried out to ten significant digits. The ratio of per capita PI for 2018 over the per capita PI for 2013 is estimated to be 1.2059028167 (that is, per capita income growth of about 20.6 percent). This reflects an increase of about 4.5 percent relative to the increase for 2013 to 2017 (1.2059028167/1.1540603665) used in the 2019 Payment Notice final rule.

Thus, using the 2019 premium adjustment percentage finalized in this rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2018 is 1.2516634051/1.2059028167, or 1.0379471610. This results in a required contribution percentage for 2019 of 8.00 * 1.0379471610 or 8.30 percent, when rounded to the nearest one-hundredth of one percent, an increase of 0.25 percentage point from 2018 (8.30358–8.05317).

We sought comment on whether there are other measures of premium growth or income growth that we could use to calculate the required contribution percentage.

Comment: We received no comments on other measures of premium growth or income growth that we could use to calculate the required contribution percentage. One commenter supported the current methodology, saying it provides consistency and stability, given highly volatile premiums.

Response: We are finalizing the required contribution percentage as proposed.

8. Eligibility Process for Exemptions

Section 155.610(h)(2) describes the timeframe during which the Exchange will accept an individual's application for a hardship exemption. We proposed to make a technical correction to § 155.610(h)(2) to reflect the prior redesignation of paragraph § 155.605(g)(1), which describes the criteria for a hardship exemption, to § 155.605(d)(1) in the 2017 Payment Notice.[55]

Commenters did not oppose this correction, and we are finalizing as proposed.

9. Exchange Functions: Small Business Health Options Program

We previously interpreted the PPACA's provisions regarding the SHOPs to require that all SHOPs provide for employer eligibility, employee eligibility, and certain enrollment functions, including premium aggregation functions.

As we have stated in previously released guidance,[56] the FF–SHOPs and the SBE–FPs for SHOPs have seen lower than expected enrollment, to date. As of January 1, 2017, approximately 7,554 employer groups were enrolled in the FF–SHOPs, covering 38,749 lives. Further, we recognize that many SHOPs, including FF–SHOPs, continue to face challenges and, to accommodate those challenges and to provide SHOPs with more flexibility in operating their programs, we proposed to allow SHOPs to operate in a leaner fashion beginning for plan years beginning on or after January 1, 2018. We are generally finalizing the policies as proposed, and describe changes to certain of the regulations later in this section of the preamble. These changes will be effective as of the effective date of this rule. In the 2018 Payment Notice, HHS finalized the removal of a participation provision that had required certain QHP issuers to participate in an FF–SHOP in order to participate in an FFE. As a result, HHS expected a significant decrease in the number of issuers in the FF–SHOPs in the 2018 plan year and fewer enrollments in the FF–SHOPs and SBE–FPs for SHOP. With the significant decreases in SHOP QHP issuer participation and enrollment for plan year 2018, and, due to lower than expected enrollment in the FF–SHOPs and SBE–FPs for SHOP to date, it is not cost effective for the Federal government to continue to maintain certain FF–SHOP functionalities, collect significantly reduced user fees on a monthly basis, maintain the technologies required to maintain an FF–SHOP website and payment platform, generate enrollment and payment transaction files, and perform enrollment reconciliation.

We proposed to remove regulatory burden on SHOPs by removing several of the existing requirements imposed upon the SHOPs, focusing on removing requirements to provide certain functionality that is not expressly required by the PPACA, while still ensuring appropriate implementation of statutorily required functions of the SHOP. Under the proposals, employer groups that are currently enrolled in a SHOP QHP for plan years that began prior to January 1, 2018, would not be affected by the proposed changes to enrollment through a SHOP. We are generally finalizing this rule as proposed, and describe changes to certain of the regulations later in this section of the preamble. The changes will take effect for plan years beginning on or after January 1, 2018, as of the effective date of this rule.

Under the approach we proposed and are finalizing, SHOPs will no longer be required to provide employee eligibility, premium aggregation, and online enrollment functionality for plan years beginning on or after January 1, 2018, effective on the effective date of this rule. The FF–SHOPs, and SBE–FP for SHOPs, will take advantage of these flexibilities. Despite the removal of several regulations on SHOPs, State Exchanges will continue to have the flexibility to operate their SHOPs as they choose, in accordance with applicable Federal and State law. Notably, we received comments to the Request for Information that provided support for this proposed enrollment approach. Moreover, a few State Exchanges currently utilize a similar enrollment approach as is being finalized as a transitional measure that was expected to extend through plan years beginning in 2018. These SBEs have already inquired about continuing to permit enrollment of their SHOP

rounded to the nearest one-hundredth of one percent.

[54] For any given year, the premium adjustment percentage is the percentage (if any) by which the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for the preceding year exceeds the most recent NHEA estimate of per enrollee employer-sponsored insurance premiums for 2013.

[55] 81 FR 12346 (March 8, 2016).

[56] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/The-Future-of-the-SHOP-CMS-Intends-to-Allow-Small-Businesses-in-SHOPs-Using-HealthCaregov-More-Flexibility-when-Enrolling-in-Healthcare-Coverage.pdf.*

consumers through a participating QHP SHOP issuer, or a SHOP-registered agent or broker, for plan years beginning in 2019 and beyond.[57] Additionally, these SBEs have each indicated that this enrollment method has contributed to reduced SHOP Exchange programmatic expenses, which is critical for SBEs to maintain financial sustainability as required by section 1311(d)(5)(A) of the PPACA.

We are finalizing the modifications throughout the requirements applicable in the SHOPs for plan years beginning on or after January 1, 2018, effective on the effective date of this rule. However, because some groups' plan years that begin prior to the effective date of this final rule will continue beyond the effective date of this rule, both the existing requirements applicable to plans beginning before January 1, 2018, and the new requirements applicable to plans beginning after January 1, 2018 will need to be in place simultaneously. For this reason, we are finalizing our proposal to make many of the existing regulatory sections regarding SHOP applicable for plan years beginning prior to January 1, 2018 only, and new regulatory sections applicable for plan years beginning on or after January 1, 2018. After the effective date of this rule, the new regulatory sections will be effective for all 2018 plans, regardless of whether the plans started prior to the effective date of the rule. Except as described in this rule, we proposed and now finalize that these new regulatory sections will mirror the existing regulatory sections.

Specifically, we proposed to amend §§ 155.705, 155.715, 155.720, 155.725, 155.730, 155.735, 155.740, 156.285 and 157.205 to make each section applicable only to plan years beginning prior to January 1, 2018. Additionally, we proposed to introduce mirroring new sections, applicable for plan years beginning on or after January 1, 2018, at §§ 155.706, 155.716, 155.721, 155.726, 155.731, 155.741, 156.286 and 157.206. We did not propose a new section mirroring current § 155.735, as further explained later in this preamble. We also proposed minor changes to § 155.700. These are described in the sections that follow. We also proposed additional changes related to the proposed new approach to SHOP in §§ 155.106, 155.200, and 156.350, to define the streamlined enrollment approach that groups enrolling in a SHOP QHP in an SBE–FP for SHOP will take when this rule becomes effective. In light of the substantial changes, we have made conforming amendments and updated applicable cross references in these and other regulations, including §§ 147.102, 147.104, 155.500, 156.200, and 156.340.

We are finalizing the following policies as proposed. SHOPs that opt to operate in a leaner fashion, such as the FF–SHOPs, will still assist qualified employers who are small employers in facilitating the enrollment of their employees in QHPs offered in the small group market in the State, consistent with section 1311(b)(1)(B) of the PPACA, because the basic functionalities of an Exchange will still be provided. SHOPs will continue to be required to certify plans for sale through a SHOP, and the following features will still be available: An internet website that displays and provides QHP information, a premium calculator that generates estimated prices of the available QHPs, and a call center to answer questions related to the SHOP. Further, small employers will continue to obtain an eligibility determination from the SHOP website but will enroll in a SHOP QHP by working with a SHOP-registered agent or broker, or with a QHP issuer participating in a SHOP to complete the enrollment process.

An enrollment completed by working with a SHOP-registered agent or broker, or with a QHP issuer participating in a SHOP in the SHOPs that decide to operate in a leaner fashion, like the FF–SHOPs, will be considered to be an enrollment through a SHOP, and an employer will be considered to have offered its employees coverage through a SHOP for purposes of section 45R of the Code (the Small Business Health Care Tax Credit), if the employer: (1) Obtains from the SHOP a favorable determination of eligibility to participate in the SHOP; (2) enrolls in a SHOP QHP offered by an issuer; and (3) chooses to have the enrollment identified as being through the SHOP. If an enrollment meets this definition, the QHP issuer will be required to conduct enrollment with all applicable SHOP rules and policies.

Because SHOPs will be required to determine employer eligibility to participate in a SHOP only, and will not be required to determine employer group members' eligibility to enroll, SHOPs will only be required to handle appeals as they relate to an employer's eligibility in a SHOP, as currently described in § 155.740. If, under the flexibilities described here, employer group members enrolled in a SHOP QHP needed to file an appeal related to their SHOP coverage, they generally will file the appeal directly with the insurance company, or could take advantage of other appeals mechanisms under applicable State and Federal law. If an employer group member enrolled in coverage though a SHOP operating under the flexibilities outlined in this rule and believes that he or she were entitled to a SHOP special enrollment period, but was denied that special enrollment period, the employer group member could file a complaint with the SHOP and the SHOP will investigate. SHOP special enrollment periods will continue to be available to enrollees who experience specified qualifying events. SHOPs that use the new flexibilities, such as the FF–SHOPs, will no longer have the information required to determine employer group members' eligibility for special enrollment periods. Therefore, issuers wishing to participate in such a SHOP will be required to administer special enrollment periods.

SHOPs opting to operate in a leaner fashion, like the FF–SHOPs, will continue to provide employers with the option to offer a choice of plans, consistent with section 1312(a)(2) of the PPACA, by continuing to allow employers to offer their employees a choice of plans, either by coverage level, or, in some States, by participating QHP issuer. Employers will be able to see the SHOP plans available, by coverage level and issuers, in their area using the plan comparison tool available on a SHOP website. Employers who choose to offer a choice of plans to employees would contact the participating QHP issuers whose plans they would like to offer to their employees to obtain the application information necessary in order to enroll in coverage.

Once the necessary information required to enroll is obtained from the QHP issuer or issuers or from the SHOP-registered agent or broker, the employer could disseminate the application information to its employees. The employer could later collect the information from its employees and send it to the applicable QHP issuer or issuers or the SHOP-registered agent or broker. Employers generally will also be responsible for collecting monthly premium payments from employees and sending them to the appropriate issuers. While initially offered to support employers' option to offer a choice of plans across issuers, premium aggregation functions are not a function mandated by the PPACA and therefore may be altered or removed, as previously proposed and now finalized with this rule. SHOP-registered agents and brokers will be able to assist employers in performing these tasks, if

[57] Extension of State-based SHOP Direct Enrollment Transition (April 18, 2016), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/1332-and-SHOP-Guidance-508-FINAL.pdf.*

the employer chooses to work with a SHOP-registered agent or broker.

Additionally, to further support employers' option to offer a choice of plans across issuers, under the proposals we are finalizing, an employer's minimum participation rate will continue to be calculated at the employer level, though the SHOPs will not be required to calculate it, and the FF–SHOPs will no longer calculate it. No changes were proposed to the way in which an employer's minimum participation rate is calculated or to the 70 percent minimum participation rate default in FF–SHOPs. Participating QHP issuers will not be permitted to deny enrollment on the basis of failure to meet minimum participation requirements to employers who have been determined eligible to participate in the SHOP, and who have met the applicable minimum participation rate, as specified by the SHOP, even if only one employee in a group wishes to enroll with a particular issuer.

Under the approach we proposed and are finalizing, SHOPs will also still be able to administer the provision at section 1304(b)(4)(D) of the PPACA that guarantees continuing eligibility for growing small employers by limiting the validity of an employer's eligibility determination such that it terminates when the employer makes a change that could end its eligibility under § 155.710(b), by requiring the employer to submit a new single employer application to the SHOP if the employer makes a change that could end its eligibility under § 155.710, and by requiring issuers to be able to distinguish SHOP enrollments from non-SHOP enrollments. Under the flexibilities being finalized, issuers will be expected to rely on the determination of eligibility to reflect the employer's ongoing eligibility to participate in the SHOP, and the IRS will have the option to follow up with an employer for additional information if necessary.

HHS understands that the changes outlined in this final rule will allow SHOPs to adopt changes (and that the FF–SHOPs will adopt such changes) that result in a substantial departure from current operations for participating SHOP QHP issuers, employers, and enrollees. It is important to note that employer groups enrolled in a SHOP plan that began in 2017 in a SHOP that will opt to operate in a leaner fashion, like the FF–SHOPs, will not be affected until their plan year ends, as the current regulations will be in effect for the entirety of a plan that began in 2017. We recognize that some employers have already completed an enrollment that took effect on or after January 1, 2018. The current regulations will also be in place for the beginning of plan year 2018 for those plans that start before the effective date of this rule. But, after the effective date of this rule, the finalized regulations pertaining to plan year 2018 will be effective for all plans that begin or began in 2018, regardless of whether the enrollment occurred prior to the effective date. HHS acknowledged that this transition would create challenges and was concerned about employers enrolling between when rates become available for plan years beginning in 2018 and when the flexibilities in this rule will go into effect. We sought comment on how to best ease this transition and did not receive any comments on this point. In addition, we released guidance on this issue in conjunction with the release of the proposed rule.[58]

Because many comments focused on the general approach we had proposed for SHOPs, we have summarized comments related to SHOP proposals here, with a few exceptions, rather than after summarizing the proposed amendments to each section.

Comment: Many commenters supported our proposal to remove many of the regulatory requirements imposed upon SHOPs. Some commenters expressed concern over our proposal to remove the regulatory burden on SHOPs, stating that removing such requirements does not address the reasons the SHOP Exchanges have been unattractive to small employers. We received a comment specifically noting that SHOPs saw low enrollment for reasons other than a poor enrollment system. Some commenters requested that HHS should require that State Exchanges either operate entirely under the SHOP regulations prior to them being amended or otherwise identically to how the FF–SHOP will operate. We also received a comment stating that removing many of the requirements on SHOPs will also do away with a centralized system for free and impartial information for small employers looking for coverage. One commenter noted that the proposals would impose an additional burden on agents, brokers, and issuers without providing additional compensation.

Response: We are finalizing the policies as proposed, with minor, mostly non-substantive adjustments further described in the following sections of the preamble. The primary purpose of these regulatory changes was not to increase the attractiveness of SHOPs to small employers, but to remove the regulatory burden on SHOPs to give Exchanges the flexibility to operate their SHOPs in a cost-effective way that best meets the needs of their State's small group market. We believe this rule achieves that primary purpose. Nonetheless, under this rule, SHOPs will continue to offer a centralized system that will provide certain free and impartial information to small employers looking for coverage. For example, all SHOPs, including FF–SHOPs, will still be required to make a premium calculator available. This calculator will provide small employers seeking SHOP coverage with free and impartial information about the SHOP QHP and stand-alone dental plan QHP options available in their area. With regard to any burden on agents, brokers, and issuers, we believe that the proposed changes will reduce, rather than increase, the burden for agents, brokers and issuers. For example, in SHOPs that use the finalized flexibilities, issuers will no longer be required to maintain the infrastructure to connect with SHOPs, and agents and brokers who assist small groups in enrolling in SHOP coverage will use the issuer enrollment channels they are most familiar with, not a SHOP website. As previously noted, given the reduction in issuer participation in the SHOPs, HHS believes the impact of removing the requirement to maintain premium aggregation functions, which the FF–SHOPs and SBE–FPs for SHOP will no longer have, will be minimal. HHS also notes that State Exchanges are encouraged to continue to operate their SHOPs as they do today, or design a SHOP within the bounds of the flexibilities being finalized within this final rule.

Comment: We received comments seeking clarification on the applicability of other Exchange requirements to SHOPs where we did not explicitly propose changes. Specifically, we received comments requesting clarification on whether HHS will collect SHOP enrollment data under § 155.1200(b)(2) from either States or issuers, in States where the Exchange pursues the flexibilities outlined herein, such as the FF–SHOP States. We also received a comment seeking clarification on whether States that operate under the flexibilities described herein would be required to perform enrollee satisfaction surveys, as described under § 155.200(d).

Response: HHS recognizes that Exchanges that operate under these

[58] CMS to Allow Small Businesses and Issuers New Flexibilities in the Small Business Health Options Program (SHOP) For Plan Year 2018 (October 27, 2017), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/New-Flexibilities-SHOP-2018.pdf.*

SHOP flexibilities may not have records of SHOP enrollments, and as such, does not expect these Exchanges to submit SHOP enrollment data to HHS under § 155.1200(b)(2). QHP issuers are required to contract with an HHS-approved enrollee satisfaction survey vendor to administer the enrollee satisfaction survey of QHPs' enrollees, and Exchanges, including SHOPs, are merely required to continue overseeing implementation of the enrollee satisfaction surveys, as described at § 155.200(d).

a. Standards for the Establishment of a SHOP (§ 155.700)

Section 155.700 outlines the general requirements to establish a SHOP and defines certain terms specific to SHOPs. We proposed to amend § 155.700(a) by adding paragraph (a)(1) to make the current requirements applicable for only plan years beginning prior to January 1, 2018. We proposed to add paragraph (a)(2) to describe the general requirements applicable for plan years beginning on or after January 1, 2018. Proposed paragraph (a)(2) more closely aligns with the statutory language in section 1311(b)(1)(B) of the PPACA than existing paragraph (a), and will specify that SHOPs must assist qualified employers in facilitating the enrollment of their employees in small group market QHPs. We believe that the PPACA does not have to be interpreted to require SHOPs to process the enrollment of qualified employees into QHPs, as is required by the current regulation. Instead, we believe it can also be interpreted in a less burdensome way, to require SHOPs to assist qualified employers in facilitating employees' enrollment into QHPs, which will still be provided for under our proposals. We sought comment on this proposal.

We are finalizing as proposed; these changes will be effective as of the effective date of this rule. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

b. Functions of a SHOP (§ 155.705) for Plan Years Beginning Prior to January 1, 2018 (§ 155.705)

As discussed in the following section, we proposed to modify the regulatory requirements regarding functions of a SHOP for plan years beginning on or after January 1, 2018, and to introduce those requirements in a new § 155.706. To reflect the proposal that the requirements currently in § 155.705 will apply only for plan years beginning before January 1, 2018, we proposed to amend the heading of § 155.705 and add paragraph (f), to state that the section would apply only for plan years that begin prior to January 1, 2018. We discuss new § 155.706 below.

We are finalizing this policy as proposed. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

c. Functions of a SHOP for Plan Years Beginning on or After January 1, 2018 (§ 155.706)

Section 155.705 describes required Exchange functions that are specific to SHOPs. To permit SHOPs to operate in a leaner fashion for plan years beginning on or after January 1, 2018, we proposed several changes to the required functions of a SHOP to become effective as of the effective date of this rule. Under these proposals, which we proposed to introduce in new § 155.706, certain functions that are currently required would become optional for SHOPs for plan years beginning on or after January 1, 2018, and the FF–SHOPs would not provide them. With the exception of the proposed changes to the functions described here, the functions would remain the same as in § 155.705. We proposed only to include the paragraphs in current paragraph (b)(3) of § 155.705, that would be applicable to plan years beginning on or after January 1, 2018, maintaining the currently applicable policy requiring SHOPs to allow employers to select a level of coverage and to offer a choice of QHPs across that level of coverage, and permitting SHOPs to allow employers to offer a choice of all QHPs from a single issuer, or another method of providing employer choice. To provide additional flexibility, we also proposed to codify that State Exchanges may, as the FF–SHOPs have, offer employers a choice of SADPs in their SHOPs. To reflect the proposals described in § 156.150(b) of this document, we proposed that State Exchanges could, and FF–SHOPs would, allow employers to offer a choice of SADPs in their SHOP. If no SADP coverage levels are available, employers would be able to offer a choice of all SADPs offered in an area. We also proposed conforming amendments to the structure of this paragraph.

Because, as discussed earlier in this preamble, premium aggregation functions are not mandated by the PPACA and to maximize the flexibilities associated with operating a SHOP, we proposed to remove required functions related to premium aggregation. Specifically, we proposed that the only premium aggregation function from § 155.705(b)(4) that would be applicable in plan years beginning on or after January 1, 2018, would be an amended version of the function in § 155.705(b)(4)(ii)(A), relating to the continuation of coverage. State Exchanges would be permitted to continue providing remaining premium aggregation functions in their SHOPs currently described at § 155.705(b)(4) if they choose to do so. SHOPs electing not to provide premium aggregation functions, like the FF–SHOPs, would still be required to provide an opportunity for employers to offer employees a choice of plans. In SHOPs not offering premium aggregation functions, we stated that we expected that employers generally would receive premium bills from each of the plans or issuers with which an employee enrolls and will pay premiums to each such plan or issuer. Section 155.705(b)(4)(ii)(A) (which we proposed to include in a revised form in § 155.706) describes the process through which the SHOP may enter into an agreement with a qualified employer related to the administration of continuation coverage. Under the approach for enrollment in a SHOP QHP for plan years beginning on or after January 1, 2018, the FF–SHOPs would no longer facilitate the collection of premiums. Therefore, we proposed that § 155.706(b)(4) would mirror § 155.705(b)(4)(ii)(A), but would not include the provision that permits the FF–SHOPs to limit the service to the collection of premiums related to the requirements under 29 U.S.C. 1161, *et seq.*

Paragraph (b)(7) of § 155.705 describes the SHOP function related to QHP availability in merged markets and paragraph (b)(8) describes the function related to QHP availability in unmerged markets. We proposed to include these functions in § 155.706(b)(7) and (b)(8).

However, under the proposal to streamline SHOP enrollment for plan years beginning on or after January 1, 2018, we proposed to change the references to a ''qualified employee'' to an ''employer group'' in both paragraphs, as the SHOP would no longer be required to process employee enrollments.

Paragraph (b)(10) of § 155.705 establishes requirements related to minimum participation rates and SHOP coverage; we proposed to include these requirements in § 155.706(b)(10), with certain modifications. In order to facilitate employers' ability to offer employees a choice of plans through a SHOP, as is required under section 1312(a)(2) of the PPACA, § 155.705(b)(10) requires that any

minimum participation rate applicable in a SHOP be calculated based on the rate of employee participation in the SHOP, rather than on the rate of participation in any particular QHP or QHPs of any particular issuer. In the FF–SHOPs, this requirement has been implemented through the requirements currently outlined at § 155.705(b)(10)(i)–(iii). Currently, the FF–SHOPs calculate a group's minimum participation rate based on the information provided by the employer and the employees during online enrollment. Under the approach we proposed, SHOPs would not be required to collect the enrollment information needed to calculate a group's minimum participation rate. Issuers would be permitted to use their established practices allowed under State law for groups enrolling in their certified SHOP plans for plan years beginning on or after January 1, 2018, so long as they comply with § 147.104, and so long as the minimum participation rate is calculated based on the level of participation in the SHOP instead of on the level of participation in any one QHP or with any one issuer (that is, so long as SHOP participation is measured at the employer group level). We did not propose to make any changes to the way in which the minimum participation rate in SHOPs is calculated or the default 70 percent minimum participation rate used in the FF–SHOPs unless otherwise determined by a State. Issuers participating in the FF–SHOPs would be required to adhere to the level of participation as would continue to be specified in § 155.706(b)(10), and issuers offering QHPs in State Exchanges would be subject to any minimum participation rate established by the SHOP, consistent with this provision. We also proposed that § 155.706(b)(10) would not include the language in § 155.705(b)(10)(i) because it applies to plan years beginning before January 1, 2016, and would therefore not be applicable for the period covered in § 155.706. We also proposed to clarify that, under the proposed approach, the reference in proposed § 155.706(b)(10) to the time the employer submits the SHOP group enrollment would be interpreted to mean the time when the employer submits a complete group enrollment or renewal to the QHP issuer or SHOP-registered agent or broker, if applicable.

Section 155.705(b)(11) specifies the requirements related to an online premium calculator. For plan years beginning on or after January 1, 2018, we proposed to modify these requirements and include the modified requirements in § 155.706(b)(11). Specifically, § 155.706 (b)(11) would specify that the premium calculator described in § 155.205(b)(6) must facilitate the comparison of available QHPs. This would reflect that SHOPs would no longer be required to maintain enrollment and premium payment information or administer premium billing, and therefore, would no longer necessarily have employer contribution information. SHOPs would be required to maintain a calculator that facilitates the comparison of available QHPs and would generate premium estimates, but would no longer be required to reflect any employer contribution. Therefore, we proposed to not include the requirements in § 155.705(b)(11)(i) or (ii) in § 155.706(b)(11), since these reflect methods SHOPs would use for determining employer contributions. In the FF–SHOPs, this premium calculator would be where an employer or SHOP-registered agent or broker could go to see a complete listing of all the QHPs available in a given area. The tool has served and would continue to serve as a resource for employers and SHOP-registered agents and brokers. Because we believe the premium calculator requirement at section 1311(d)(4)(G) of the PPACA could be interpreted to apply to only individual market Exchanges based on its reference to APTCs and CSRs, which are not available through SHOPs, we believe that this proposal is consistent with the statute.

Section 155.705(c) generally requires a SHOP to provide data related to eligibility and enrollment of a qualified employee to the applicable individual market Exchange. For plan years beginning on or after January 1, 2018, we proposed that this requirement would apply only in SHOPs that collect employee enrollment data related to eligibility and enrollment of a qualified employee, unless the SHOP is operated pursuant to § 155.100(a)(2).

Finally, we proposed in paragraph (e) that the provisions of the section would be applicable for plan years beginning on or after January 1, 2018.

We are finalizing these policies as proposed, except that we are finalizing minor changes to reflect the changes to the actuarial value requirements for SADP QHPs in § 156.150 of this rule, and small, nonsubstantive changes to the regulatory text for clarity and consistency; these policies will be effective as of the effective date of this rule.

Comment: We received a few comments regarding the minimum participation rate in SHOPs. One commenter requested that we maintain the 70 percent minimum participation rate in FF–SHOPs, and another requested that the 70 percent minimum participation rate be lowered. We also received a comment disagreeing with the intent of the proposals within this section. A commenter noted that groups that do not meet the minimum participation rate should not be permitted to enroll in coverage. Finally, a commenter requested that HHS continue to promote the annual 1-month window in which the minimum participation rate does not apply.

Response: In our proposed changes to SHOPs, we did not propose to change the applicable minimum participation rate, or the way in which the minimum participation rate is calculated. The FF–SHOPs will continue to maintain a minimum participation rate of 70 percent unless otherwise specified by the State. This percentage is consistent with industry standards. The annual 1-month window from November 15–December 15, when employers can enroll in a SHOP QHP without meeting any minimum participation rate for their State, will remain in place. This window aligns with the guaranteed availability standards outlined in the PPACA.

Comment: We received a comment in support of our proposal to codify an employer's ability to offer a choice of SADPs and our proposal to allow employers to offer a choice of all SADPs offered through a SHOP, in accordance with the proposals made elsewhere in this rule to remove actuarial values for SADPs.

Response: We are finalizing this policy as proposed, with revisions to the regulation text to reflect the changes to the actuarial value requirements for SADP QHPs, as noted in the proposed rule, and to clarify that the third option refers to all SADPs offered in an area by a single issuer. We also added a title for paragraph (b)(4) that was inadvertently omitted in the proposed rule.

Comment: We received a comment requesting that the option for States to submit an annual letter opting out of the third method of employee choice, a choice of all plans offered by a single issuer, be removed.

Response: We did not propose to remove this option in the proposed rule, and are finalizing this section as described earlier in the preamble for this section. We continue to believe it is important for States to have a choice regarding whether employee choice of all QHPs offered by a single issuer applies in their markets.

Comment: One commenter noted that without premium aggregation, it is difficult or impossible for small businesses to offer a choice of multiple

insurers and plans to their employees. The commenter recommended that HHS provide data on the number of employers currently offering employee choice in the FF–SHOPs and provide annual updates on that data, so that HHS, stakeholders, and policymakers can monitor the impact of this change on employee choice in SHOP.

Response: As discussed throughout this preamble, HHS believes that the PPACA does not have to be interpreted to require SHOPs to provide premium aggregation functions and thus is finalizing the proposals to allow SHOPs to not provide premium aggregation functions other than those related to continuation of coverage under finalized § 155.706(b)(4). State SHOPs are permitted to continue offering premium aggregation functionality. While we recognize that the elimination of premium aggregation in the FF–SHOPs could increase the administrative burden on employers, we believe that potential increased burden is outweighed by the other benefits to the SHOPs and, ultimately, to the employers described throughout this preamble regarding the changes to the SHOPs. Under the proposals being finalized in this rule, SHOPs will not be required to have access to ongoing enrollment information, and the FF–SHOPs will not require issuers to report SHOP employee choice enrollment information to HHS.

d. Eligibility Determination Process for SHOP for Plan Years Beginning Prior to January 1, 2018 (§ 155.715)

As discussed in the following section, we proposed to modify the regulatory requirements regarding the eligibility determination process for SHOP for plan years beginning on or after January 1, 2018, effective on the effective date of this rule, and to introduce those requirements in a new § 155.716. To reflect that the requirements currently in § 155.715 will apply only for plan years beginning before January 1, 2018, we proposed to amend the heading of § 155.715 and add paragraph (h), to state that the section applies only for plan years that begin prior to January 1, 2018.

We are finalizing this section as proposed. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

e. Eligibility Determination Process for SHOP for Plan Years Beginning on or After January 1, 2018 (§ 155.716)

Section 155.715 describes the SHOP eligibility determination process for employers and employees. We proposed to add new § 155.716 to describe the eligibility determination process for SHOPs for plan years beginning on or after January 1, 2018. With the exception of the changes to the process described here, the process will remain the same as in § 155.715. However, this new section will modify and remove some of the requirements in § 155.715. The proposals described in this section will be effective on the effective date of this rule.

Section 155.715(a) requires that before permitting the purchase of coverage in a QHP, a SHOP must determine that the employer or individual who requests coverage is eligible. This requirement means that employers and employees must complete an application to participate in a SHOP. Accordingly, the FF–SHOPs have established certain operational requirements related to submitting an application through the FF–SHOP website, including providing information on the business (including location, Employer Identification Number, and number of employees), and identity verification.

To reduce the barriers on employers to obtain SHOP coverage, we proposed in § 155.716 that SHOPs must determine that the employer who requests coverage is eligible, but that SHOPs generally would not always need to do so before the issuer permits the purchase of coverage in a QHP through a SHOP, for plan years beginning on or after January 1, 2018. This would generally permit an employer to purchase a QHP before obtaining a determination of SHOP eligibility and confirming with the issuer the status of the enrollment as being through the SHOP. As further explained in the preamble to § 156.286, issuers would be expected to establish processes to ensure that they can accurately identify which enrollments are considered SHOP enrollments and which are not. We encouraged employers to obtain an eligibility determination from a SHOP as close to the date in which they purchase a SHOP QHP as possible. We considered establishing a limit on how long an employer can wait between purchasing the QHP and obtaining the determination of eligibility for that QHP to be considered purchased through the SHOP. We solicited comments on whether to establish such a limit, and how long it should be. Ultimately, we are finalizing this policy as proposed, and are not establishing a timeline under which employers must obtain an eligibility determination from a SHOP for their enrollments to be considered through the SHOP.

As a condition of claiming the Small Business Health Care Tax Credit, small employers must be prepared to provide sufficient proof that they meet applicable criteria. Part of the employer's responsibility in providing evidence that it is a small employer eligible for the Small Business Health Care Tax Credit includes the ability to verify not only the purchase of a SHOP QHP, but the ability to produce a favorable eligibility determination from a SHOP. Therefore, employers applying for the Small Business Health Care Tax Credit are also encouraged to obtain an eligibility determination from the SHOP in the taxable year in which they intend to apply for the credit.

Section 155.715(b) requires the SHOP to accept SHOP applications from both employers and employees, and § 155.715(c) provides for the verification of both employer and employee eligibility. For plan years beginning on or after January 1, 2018, we proposed to provide SHOPs flexibility to forgo providing for employee eligibility determinations and related functionality and obligations (and the FF–SHOPs will pursue this flexibility). We proposed that SHOPs would not be required to accept applications by employees or determine eligibility of employees because, under the proposed approach to enrollment in a SHOP, SHOPs will not be required to interact with employees. Proposed paragraphs (b) and (c) of § 155.716 would still require SHOPs to accept a SHOP single employer application form from employers, and to verify employer eligibility subject to provisions like those currently in § 155.715(c)(2) through (4). We have updated and made available a single employer application that SHOPs can use to determine employer eligibility to participate in the SHOP to reflect the new rule at § 155.731, described elsewhere in this preamble. Currently, employee information is primarily collected for purposes of enrollment, and therefore will not be necessary for SHOPs to collect under the approach we are finalizing, allowing SHOPs to operate in a leaner fashion. State Exchanges that intend to maintain more robust SHOP functionalities, in lieu of the flexibilities adopted in this rule, will be permitted to continue to determine employee eligibility. We believe this proposal is consistent with the statute because, as noted above, the PPACA does not have to be interpreted to require SHOPs to provide for employee enrollment functionality, and does not define qualified employees.

Paragraph (d) of § 155.715 describes the eligibility adjustment period. We proposed to include in § 155.716(d) these requirements as they relate to eligibility for employers. However,

because SHOPs will not be required to accept applications from employees, we proposed not to include the requirements in § 155.715(d)(2), relating to eligibility for employees, in new § 155.716. We also proposed to add language to reflect that SHOPs also must address inconsistencies in employer eligibility information received from sources other than those used in the employer eligibility process described in § 155.715(c).

To reflect our proposed changes to the employer eligibility verification process, as further described in this section and in the preamble to § 157.205, and our proposal not to include a section mirroring § 155.735 regarding terminations, we are adding a requirement in the paragraphs mirroring paragraphs (d)(3)(i) and (e) of § 155.715 to require the SHOP to notify employers not only of a denial of the employer's eligibility to participate in the SHOP, but also of a termination of the employer's eligibility to participate in the SHOP.

Paragraph (f) of § 155.715 specifies the requirement that the SHOP notify an employee of his or her eligibility to enroll in a SHOP. Because we will not be requiring SHOPs to determine employee eligibility for plan years beginning on or after January 1, 2018, we proposed not to include this requirement in § 155.716. SHOPs that continue to provide employee eligibility functionality should continue notifying employees of their eligibility. In the SHOPs that operate in a leaner fashion, like the FF–SHOPs, we anticipate that the participating QHP issuer or employer will determine the method of employee enrollment and notification, consistent with otherwise applicable Federal or State law.

Paragraph (g) of § 155.715 describes the requirements surrounding communication between the SHOP and QHP issuers in the event of an employer withdrawing from the SHOP and the notification of qualified employees of an employer's withdrawal from SHOP. Under the proposed approach for SHOPs beginning for plan years that begin on or after January 1, 2018, the enrollment and disenrollment processes would be addressed between the employer and the issuer or the agent or broker. Therefore, we proposed not including these requirements in § 155.716.

We further proposed in paragraph (f) of § 155.716 that an employer's determination of eligibility to participate in the SHOP obtained under paragraph (a) remains valid until the employer makes a change that could end its eligibility under § 155.710(b). This could include terminating offers of coverage to employees maintaining full-time status, growing to be a large employer without having maintained continuous SHOP coverage, or moving its principal business address or eligible employee worksites out of the SHOP service area. The employer will be required under new regulations being finalized in part 157 to take further action upon termination of the validity of the determination of eligibility to participate in a SHOP to submit a new application for determination of eligibility or to withdraw from participation in the SHOP. We considered requiring SHOPs to acknowledge an employer's withdrawal from participation in the SHOP within a reasonable time. Alternatively, we considered requiring that employers reapply to determine their SHOP eligibility on an annual basis. We sought comment on these proposals, and ultimately are moving to finalize our proposal without requiring employers to reapply to determine their SHOP eligibility on an annual basis or requiring SHOPs to acknowledge such a withdrawal.

We proposed to specify in paragraph (g) that the provisions in § 155.716 will be applicable for plan years beginning on or after January 1, 2018.

We are finalizing these policies as proposed. These changes will become effective as of the effective date of this rule.

Comment: We received several comments urging us not to establish a 30-day timeline on employers to obtain an eligibility determination because the timeframe would be burdensome on employers. We received comments from State Exchanges also recommending that no timeline should be established for SHOP. These State Exchanges do not impose such a timeline in their SHOPs and have found success with the model.

Response: We are finalizing this section as proposed, and no timeline will be imposed on employers to obtain an eligibility determination from a SHOP. We note that issuers may require employers to obtain an eligibility determination from the SHOP as a condition of enrollment when there is a legal basis for restricting enrollment to enrollment through the SHOP. Further, the IRS may request to see an employer's eligibility determination from the SHOP if the employer chooses to apply for the Small Business Health Care Tax Credit.

Comment: We received one comment regarding whether employers should be required to notify a SHOP of their intent to withdraw from a SHOP, and if a SHOP should acknowledge an employer's withdrawal. The commenter recommended that we not require employers to notify the SHOP of their intent to withdraw their participation from a SHOP and, therefore not require SHOPs to acknowledge an employer's withdrawal.

Response: Although we appreciate the commenter's suggestion as another way to ease burden on employers, for SHOPs to be able to determine which employers remain eligible to participate, the rules must impose some obligation on employers to notify the SHOP when their eligibility ends. As such, as further described in the preamble to § 157.206, we are finalizing our proposal that requires employers to submit a new single employer application to the SHOP or withdraw from participating in the SHOP if the employer makes a change that could end its eligibility under § 155.710 of this subchapter. As noted above, SHOPs will not be required to acknowledge an employer's withdrawal.

f. Enrollment of Employees Into QHPs Under SHOP for Plan Years Beginning Prior to January 1, 2018 (§ 155.720)

Section 155.720 contains requirements related to the enrollment of employees into QHPs under SHOP. To reflect that our proposed approach would no longer require SHOPs to provide functionality related to enrollment of employees for plan years beginning on or after January 1, 2018, we proposed to amend the heading of § 155.720 and add paragraph (j), to state that the section will apply only for plan years that begin prior to January 1, 2018.

Specifically, we proposed that the requirement in paragraph (b) of § 155.720 that SHOPs establish a timeline and process for QHP issuers and employers to follow regarding purchasing coverage and processing of enrollment would not be applicable for plan years that begin on or after January 1, 2018. State Exchanges that choose to maintain their current operations may continue establishing enrollment timelines, as State law and SHOP technology permit. We also proposed that the requirements to transmit enrollment information on behalf of qualified employers and employees to QHP issuers as described in current paragraph (c), and to process payments as described in current paragraph (d) would not apply after plan year 2017, since SHOPs may not have enrollment or payment information to transmit. We proposed that the requirement in paragraph (e) that SHOPs ensure a QHP issuer notifies a qualified employee enrolled in a QHP of the effective date of his or her coverage would not apply

for plan years beginning on or after January 1, 2018 because SHOPs may not have the enrollment information necessary to enforce this requirement. We anticipated QHP issuers will notify employees in accordance with applicable State law. Additionally, after plan year 2017 plans have ended, we proposed not to require SHOPs to reconcile enrollment information as described in paragraph (g), as SHOPs may not have enrollment files to reconcile with issuers. We also proposed that the requirements described in current paragraph (h), which requires a SHOP to notify a qualified employee's employer in the event the qualified employee terminates his or her SHOP coverage, would no longer apply for plan years beginning on or after January 1, 2018. Under the proposed approach, SHOPs may not have that information to communicate to the qualified employee's employer.

We are finalizing these policies as proposed. These changes will become effective as of the effective date of the final rule. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

g. Record Retention and IRS Reporting for Plan Years Beginning on or After January 1, 2018 (§ 155.721)

The approach we are finalizing will not require SHOPs to provide functionality related to enrollment of employees for plan years beginning on or after January 1, 2018, and therefore, we proposed that § 155.720 be inapplicable for those plan years, effective on the effective date of this rule. However, there are requirements in that section related to record retention and IRS reporting that will continue to be applicable with some modifications. We proposed to include modified versions of these requirements in a new § 155.721, titled ''Record retention and IRS Reporting for plan years beginning on or after January 1, 2018.''

We proposed that all SHOPs still be required to maintain records of employer eligibility for 10 years, as described in paragraph (f). Because SHOPs utilizing the proposed flexibilities, like the FF–SHOPs, would not have information on employees, we did not propose to continue requiring that SHOPs maintain information on employees.

Section 155.720(i) describes the information a SHOP is currently required to communicate to the IRS for purposes of the Small Business Health Care Tax Credit. We proposed to modify the reporting requirement for SHOPs such that for plan years beginning on or after January 1, 2018, effective on the effective date of this final rule, SHOPs would be required to send the IRS information about the employers determined eligible to purchase a SHOP QHP only upon the request of the IRS. We stated that we believe providing the IRS with a list of employers determined eligible to participate in a SHOP, at the IRS's request, fulfills HHS's reporting responsibility. As mentioned earlier in this document, employers in all States must be able to provide sufficient evidence to the IRS that they meet all the necessary eligibility requirements for the Small Business Health Care Tax Credit, if they intend to apply for it. The IRS may ask employers to produce the aforementioned evidence and employers have a responsibility to produce it. Further, we stated that employers may work with their issuer to verify their contribution information, employee enrollment information, and any other applicable information required to apply for the Small Business Health Care Tax Credit through their tax filings.

We are finalizing these policies as proposed.

Comment: Commenters were generally supportive of these proposals. One commenter disagreed with the premise of this section, citing their lack of support for the overall proposed approach to allow SHOPs to operate in a leaner fashion. We also received a comment supporting the proposals to require SHOPs to only report information to the IRS as requested. This commenter sought clarification on whether HHS will continue to collect SHOP enrollment data per § 155.1200, which was addressed earlier in this rule at the beginning of section III.D.9. Finally, one commenter expressed concern about an employer's access to claim the Small Business Health Care Tax Credit if an employer is in a county where no SHOP plans are available. The commenter noted that in the past, the IRS has granted flexibility to employers in counties that had no SHOP plans available and allowed employers to still claim the Small Business Health Care Tax Credit, if otherwise applicable.

Response: We are finalizing this section as proposed. As noted above, we believe that the information being collected under our proposals and communicating that information only as requested by the IRS is sufficient for the purposes of their administration of the Small Business Health Care Tax Credit. The Treasury Department and the IRS have jurisdiction over the Small Business Health Care Tax Credit.

h. Enrollment Periods Under SHOP for Plan Years Beginning Prior to January 1, 2018 (§ 155.725)

As discussed in the following section, we proposed to modify the regulatory requirements regarding enrollment periods under a SHOP for plan years beginning on or after January 1, 2018, and to introduce those requirements in a new § 155.726. To reflect the proposal that the requirements currently in § 155.725 would apply only for plan years beginning before January 1, 2018, we proposed to amend the heading of § 155.725 and add paragraph (l), to state that the section would only apply for plan years that begin prior to January 1, 2018. These changes would become effective as of the effective date of the final rule. We discuss the proposed new § 155.726 below.

We are finalizing these policies as proposed. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

i. Enrollment Periods Under SHOP for Plan Years Beginning on or After January 1, 2018 (§ 155.726)

Section 155.725 describes enrollment periods under SHOP, including the timeline under which employer groups must enroll in SHOP coverage, and the notices the SHOP is required to send related to enrollment periods. We proposed to introduce a new § 155.726, which would retain the rolling enrollment and minimum participation rate provisions of § 155.725(b) and (k), but would remove the requirements applicable to enrollment periods under SHOP other than those related to special enrollment periods for plan years beginning on or after January 1, 2018, to reflect the increased flexibility we proposed. The policies described in this section were proposed to be effective on the effective date of this rule.

Section § 155.725(a) requires that SHOPs ensure that enrollment transactions are sent to QHP issuers and that issuers adhere to coverage effective dates in accordance with this section. We proposed that many previously required enrollment and election periods would no longer apply for plan years beginning on or after January 1, 2018. State Exchanges that continue to provide online enrollment functionality for their SHOP will be able to continue to adhere to these requirements. However, under the proposed approach, some SHOPs (including the FF–SHOPs) may not have enrollment information to communicate to the issuers and may not want to continue setting and enforcing coverage effective dates under the

previously specified requirements. In SHOPs that pursue the full extent of the proposed approach, like the FF–SHOPs, we anticipated that most enrollment timelines, deadlines, and coverage effective dates in SHOPs would be set by employers and issuers consistent with applicable State law and otherwise applicable Federal law. We stated that we did, however, believe that, under the proposed approach, the SHOP should be responsible for ensuring that QHP issuers adhere to the remaining required enrollment periods and their corresponding coverage effective dates. Therefore, we proposed to include this requirement in § 155.726(a).

Paragraph (c) of § 155.725 states that the SHOP must provide qualified employers with an annual election period prior to completion of the employer's plan year and paragraph (d) of § 155.725 requires the SHOP to provide notice of that period in advance. Given that, under the proposed approach for SHOPs for plan years beginning on or after January 1, 2018, SHOPs would not be required to process enrollments, we proposed that these requirements would not apply for plan years beginning on or after January 1, 2018. We anticipated that participating QHP issuers in SHOPs pursuing the proposed approach, like in the FF–SHOPs, would be responsible for setting any requirements around renewals, annual employer election periods, and annual employee open enrollment periods, based on their current practices, and subject to applicable State law and otherwise applicable Federal law, including §§ 147.104 and 147.106. For similar reasons, we proposed that the requirements in § 155.725(e), which requires the SHOP to set a standard open enrollment period for qualified employees, and § 155.725(f), which requires the SHOP to send a notice to the employee about the open enrollment period, would not apply for plan years beginning on or after January 1, 2018.

Section 155.725(g) requires SHOPs to establish and maintain enrollment and coverage effective dates, including waiting periods, for newly qualified employees. However, the amendments we proposed at § 155.716 would remove the requirement for SHOPs to perform employee eligibility determinations, accept and process single employee SHOP application forms, as well as verify employee eligibility for plan years beginning on or after January 1,2018. Furthermore, our proposed amendments not to include paragraphs (c) and (d) of § 155.725 in § 155.726 would remove the requirement for SHOPs to maintain enrollment records for plan years beginning on or after January 1, 2018. SHOPs that utilize these proposed flexibilities, like the FF–SHOPs, may be unable to satisfy the requirements in § 155.725(g). To align with these proposed amendments, we proposed that the requirements in § 155.725(g) would not apply for plan years beginning on or after January 1, 2018. Instead, we anticipated that enrollment timelines, deadlines, and coverage effective dates for newly qualified employees in SHOPs that pursue the proposed approach would be set by employers and issuers consistent with applicable State law and otherwise applicable Federal law, including § 147.116. Further, as noted above, issuers offering plans in SHOPs would still be required to adhere to the guaranteed availability requirements set in § 147.104(b)(1)(i) and the special enrollment period requirements in proposed § 155.726(c).

We also proposed that the requirement in § 155.725(h)(1) that a SHOP establish the effective dates of coverage for initial and annual group enrollments would not apply for plan years beginning on or after January 1, 2018. Because SHOPs utilizing the proposed flexibilities, like the FF–SHOPs, would no longer be involved in processing group enrollments, and would therefore not be able to hold issuers accountable to these enrollment deadlines, we stated that we believed it was more appropriate to permit QHP issuers in SHOPs to set their own enrollment timelines. However, State Exchanges would be permitted to continue establishing these effective dates for their SHOPs. We also proposed to remove paragraph (h)(2) for plan years beginning on or after January 1, 2018, which establishes the effective dates for initial and annual group enrollments in FF–SHOPs, because the FF–SHOPs would utilize the proposed flexibilities. We anticipated that issuers in SHOPs that pursue this approach, like in FF–SHOPs, would set enrollment timelines for employer groups participating in these SHOPs, based on their current practices, and consistent with the market rules set forth in §§ 147.104 and 147.106, and otherwise applicable State law.

We proposed that the special enrollment periods specified in § 155.725(j) would continue to be applicable in the SHOPs for plan years beginning on or after January 1, 2018, and proposed to include these in § 155.726(c). We also proposed that the requirements regarding special enrollment periods in § 155.725(j)(3) would apply for plan years beginning on or after January 1, 2018. However, we proposed to modify the SHOPs' responsibilities with respect to special enrollment periods. As stated earlier in this preamble, under the new flexibilities for SHOPs beginning in plan years starting on or after January 1, 2018, SHOPs would no longer be required to provide functionality related to enrollment of employees. For SHOPs that pursue this flexibility, like the FF–SHOPs, issuers will preliminarily be responsible for completing enrollments, and so we expected issuers would implement enrollment periods. Therefore, we proposed to modify the requirements to reflect that the SHOP's revised role would not be to provide special enrollment periods, but to ensure that QHP issuers offering coverage through the SHOP provide the special enrollment periods set forth in regulation.

We are finalizing these policies as proposed, with one minor non-substantive change to correct the placement of numbering in the regulation text.

Comment: Some commenters requested clarification on our proposals at § 155.726(c), and recommended that the proposals better align with § 155.420, while another recommended that issuers be permitted to provide the same special enrollment periods as they provide outside the SHOP.

Response: Special enrollment periods offered through a SHOP are aligned with the special enrollment periods available in the individual market FFEs unless the special enrollment periods offered in the FFEs do not practically apply in the SHOP. We did not propose any changes to special enrollment periods in SHOPs and finalize this section as proposed.

j. Application Standards for SHOP for Plan Years Beginning Prior to January 1, 2018 (§ 155.730)

As discussed in the following section, we proposed to modify the regulatory requirements regarding application standards of a SHOP for plan years beginning on or after January 1, 2018 and to introduce those requirements in a new § 155.731. To reflect the proposal that the requirements currently in § 155.730 would apply only for plan years beginning before January 1, 2018, we proposed to amend the heading of § 155.730 and add paragraph (h), to state that the section would apply for only plan years that begin prior to January 1, 2018.

We are finalizing these policies as proposed; the policies will be effective on the effective date of the final rule. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

k. Application Standards for SHOP for Plan Years Beginning on or After January 1, 2018. (§ 155.731)

Section 155.730 describes the requirements for employer and employee applications in the SHOPs. We proposed to modify these requirements for plan years beginning on or after January 1, 2018, and to introduce these modified requirements in § 155.731. With the exception of the proposed changes to the requirements described here, the requirements would remain the same as in § 155.730.

In accordance with our approach allowing SHOPs to operate in a leaner fashion for plan years beginning on or after January 1, 2018, effective as of the effective date of this rule, QHP issuers would complete the process of enrolling qualified employees into coverage in SHOPs that will operate in a leaner fashion, like the FF–SHOPs. In those SHOPs it would not be necessary for a SHOP to collect information necessary for purchasing coverage. Therefore, we proposed to modify the information collection requirements related to the single employer application to require SHOPs to collect only information that would be necessary for SHOPs to determine employer eligibility to participate in the SHOP under § 155.710(b). To more closely align the description of the data elements collected with those standards for eligibility to participate, we proposed to require the SHOP to collect the employer name and address of the employer's locations; information sufficient to confirm that the employer is a small employer; the Employer Identification Number; and information sufficient to confirm that the employer is offering, at a minimum, all full-time employees' coverage in a QHP through a SHOP. SHOPs could collect other information, at their option subject to the limitations in § 155.716(c)(2) and § 155.731(f).

Paragraph (c) of § 155.730 requires the use of a single employee application. We proposed that this requirement would not apply for SHOP beginning for plan years starting on or after January 1, 2018, as the information collected in this application would no longer be necessary, since the SHOP would no longer be required to process employees' enrollment.

Section 155.730(d) permits a SHOP to use a model single employer application and model single employee application provided by HHS, and § 155.730(e) permits the use of HHS-approved alternatives to these model applications. We also proposed to maintain these options, but for consistency with the new approach to SHOP, we proposed not to reference a model single employee application. The model single employer application with the elements described in proposed § 155.731(b) has been updated to reflect these changes.[59]

Paragraph (g) of § 155.730 describes additional application safeguards for SHOP employer and employee applications, which we proposed to maintain in § 155.731(f) with minor amendments to reflect the proposal to eliminate the requirement to collect a single employee application. We also proposed in new paragraph (g) to state that § 155.731 would only be applicable for plan years beginning on or after January 1, 2018.

We are finalizing these policies as proposed. These changes will become effective as of the effective date of this rule.

Comment: One commenter expressed concern that our proposals to approve alternative applications will be burdensome, since applications are reviewed by the State.

Response: Section 155.731(b) discusses the application an employer submits to the SHOP for the purposes of determining eligibility to participate in a SHOP. No State review is required under § 155.731(b) (although a State Exchange could perform such a review, at its option, for its SHOP). The information that SHOPs are required to collect under these rules is minimal. HHS does not believe that additional information to determine an employer's eligibility to participate in a SHOP is necessary, and therefore maintains the ability to review any alternate application a SHOP may use to determine an employer's eligibility to participate in a SHOP. This section is being finalized as proposed.

Comment: We received one comment requesting clarification that State Exchanges can meet § 155.731(e)(2) by making an application available for download on a website as opposed to implementing an interactive web application portal.

Response: Section 155.730(e)(2) does not currently distinguish whether an employer application be available for download on an internet website as opposed to through an interactive web application portal on an internet website, so long as the tools to file an application be available on an internet website. We did not make any changes to this language in § 155.731(e)(2).

[59] Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/SHOP-Eligibility-Determination-Form.pdf.*

l. Termination of SHOP Enrollment or Coverage (§ 155.735)

Section 155.735 outlines requirements related to terminations of SHOP coverage or enrollment. Under our proposed approach, described in detail in the preamble to earlier sections of this final rule, the process of completing enrollments, as well as terminating coverage, could be completed by issuers, and would not be required to be completed by SHOPs operating in a leaner fashion under the flexibilities provided for in this rule, like the FF–SHOPs. Issuers would be expected to comply with otherwise applicable State and Federal law regarding terminating coverage, the timelines and effective dates for termination, and any notice requirements, including those at §§ 147.106 and 156.285. Accordingly, we proposed that this section would be applicable for only plan years beginning prior to January 1, 2018, as described in the proposed amendment to the heading and new paragraph (h), effective on the effective date of this rule. SHOPs maintaining current enrollment functions were encouraged to set termination guidelines and distribute notices for terminations based on nonpayment of premiums or loss of employee eligibility, unless State law requires QHP issuers to send the notices. Because SHOPs, such as the FF–SHOPs, would no longer be required to enroll groups into a SHOP QHP, they would no longer be required to maintain the ability to terminate coverage. We believe new §§ 155.716 and 157.206 sufficiently address terminations of eligibility for participation in a SHOP.

We are finalizing these policies as proposed. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

m. SHOP Employer and Employee Eligibility Appeals Requirements for Plan Years Beginning Prior to January 1, 2018 (§ 155.740)

As discussed in the following section, we proposed to modify the regulatory requirements regarding employer and employee eligibility appeals in SHOP for plan years beginning on or after January 1, 2018, and to introduce those modified requirements in a new § 155.741. To reflect the proposal that the requirements currently in § 155.740 would apply only for plan years beginning before January 1, 2018, effective on the effective date of this rule, we proposed to amend the heading of § 155.740 and add paragraph (p), to state that the section would apply only

for plan years that begin prior to January 1, 2018.

We are finalizing these policies as proposed. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

n. SHOP Employer and Employee Eligibility Appeals Requirements for Plan Years Beginning on or After January 1, 2018 (§ 155.741)

Section 155.740 describes the SHOP eligibility appeals process for employers and employees. These provisions describe the applicable definitions, the general requirements to provide for appeals, and employers' and employees' rights to appeal an eligibility determination from the SHOP.

To continue to provide for employer eligibility appeals, we proposed to add new § 155.741, mirroring § 155.740, with the following exceptions. Because we proposed elsewhere that the requirement to provide employees with eligibility determinations and the requirement in § 155.715(f) regarding notification of employee eligibility would no longer apply in plan years beginning on or after January 1, 2018, we proposed not to include a paragraph mirroring § 155.740(d), which describes employees' rights to appeal. We also proposed to omit other references to employee appeal rights, to add references to provide for appeals of terminations of eligibility to participate in a SHOP, and to update cross-references as applicable.

We proposed in paragraph (o) that the provisions of § 155.741 would only be applicable to plan years beginning on or after January 1, 2018, effective on the effective date of this rule.

We are finalizing these policies as proposed. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

E. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. FFE and SBE–FP User Fee Rates for the 2019 Benefit Year (§ 156.50)

Section 1311(d)(5)(A) of the PPACA permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. If a State does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the PPACA directs HHS to operate an Exchange within the State. Accordingly, in § 156.50(c), we specified that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month that is equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE–FPs for the applicable benefit year, and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE or SBE–FP.

OMB Circular No. A–25R establishes Federal policy regarding user fees; it specifies that a user fee charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. As in benefit years 2014 through 2018, issuers seeking to participate in an FFE in the 2019 benefit year will receive two special benefits not available to the general public: (1) The certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. These special benefits are provided to participating issuers through the following Federal activities for the 2019 benefit year in connection with the operation of FFEs:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management of a Navigator program;
- Regulation of agents and brokers;
- Eligibility determinations;
- Enrollment processes; and
- Certification processes for QHPs (including ongoing compliance verification, recertification and decertification).

OMB Circular No. A–25R further states that user fee charges should generally be set at a level that is sufficient to recover the full cost to the Federal government of providing the service when the government is acting in its capacity as sovereign (as is the case when HHS operates an FFE). Activities performed by the Federal government that do not provide issuers participating in an FFE with a special benefit are not covered by this user fee.

Based on estimated contract costs, enrollment and premiums for the 2019 benefit year, we proposed to maintain the 2019 benefit year user fee rate for all participating FFE issuers at 3.5 percent of total monthly premiums. We sought comment on this proposal.

State Exchanges on the Federal platform enter into an agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between State and Federal programs. Accordingly, in § 156.50(c)(2), we specified that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for SBE–FPs for the applicable benefit year, unless the SBE–FP and HHS agree on an alternative mechanism to collect the funds from the SBE–FP or State instead of direct collection from the SBE–FP issuers. The benefits provided to issuers in SBE–FPs by the Federal government will include use of the Federal Exchange information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs, as defined at section 1413(e) of the PPACA, and enrollment in QHPs under § 155.400. As previously discussed, OMB Circular No. A–25R established Federal policy regarding user fees, and specified that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. The user fee rate for SBE–FPs is calculated based on the proportion of FFE costs that are associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment functions, and allocating a share of those costs to issuers in the relevant SBE–FPs. A significant portion of expenditures for FFE functions are associated with the information technology, call center infrastructure, and eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs as defined at section 1413(e) of the PPACA, and personnel who perform the functions set forth in § 155.400 to facilitate enrollment in QHPs. Based on this methodology, we proposed to charge issuers offering QHPs through an SBE–FP a user fee rate of 3.0 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP. This fee would support FFE operations associated with providing the functions described above. We sought comment on this proposal.

We are finalizing the FFE and SBE–FP user fees rates at 3.5 and 3.0 percent

of monthly premiums, respectively, as proposed.

As we describe elsewhere in this rule, for plan years beginning on or after January 1, 2018, effective on the effective date of this rule, we are removing employee eligibility, premium aggregation, and online enrollment functionality through the FF–SHOPs for FFE and SBE–FP SHOP issuers. Given the changes to the functionality for the FF–SHOPs, HHS will not provide these special benefits through the FF–SHOPs or SBE–FP SHOPs after the effective date of the rule. Therefore, we proposed that HHS would not assess a user fee on issuers offering QHPs through FF–SHOPs or SBE–FP SHOPs because these user fees are only charged to issuers who receive special benefits from enrolling individuals through the Federal platform. In instances where enrollment did occur through the Federal platform, for example, for plan years beginning prior to the effective date of the final rule, HHS will continue charging SHOP issuers monthly FFE or SBE–FP user fees, as applicable. We are finalizing this policy as proposed.

Comment: Commenters noted the FFE user fee rate should decrease over time, particularly given the reduction in outreach and education activities that HHS conducts. Additionally, commenters noted that the collection and allocation of the user fees should be made more transparent. Other commenters also noted that HHS should allocate a greater portion of the user fees to outreach and education programs.

Response: The FFE and SBE–FP user fee rates for the 2019 benefit year are based on expected total costs to offer the special benefits to issuers offering plans on FFEs or SBE–FPs and evaluation of expected enrollment and premiums for the 2019 benefit year. These estimates yielded an FFE user fee rate of 3.5 percent of premiums and an SBE–FP user fee rate of 3.0 percent of premiums. We reiterate that under OMB Circular No. A–25R, collections are only spent on user fee eligible activities. We will continue to examine cost estimates for the special benefits provided to issuers offering QHPs on the FFEs and SBE–FPs for future benefit years. Additionally, outreach and education efforts will be evaluated annually and funded at the appropriate level.

Comment: Some commenters did not support the proposed SBE–FP user fee rate, stating the proportion of FFE costs allocated to SBE–FP functions do not represent market value, the fee is overstated particularly in context of reduced outreach and education functions by the Federal platform, and increased premiums due to cost-sharing reductions amounts loaded to silver premiums ought to also reduce the user fee rate. Some of these commenters also stated that HHS has not provided SBE–FPs with enrollment data or access to *HealthCare.gov* back-end customer tools that the SBE–FPs could use to improve outreach and enrollment activities at the State level. Commenters suggested that HHS maintain the 2018 benefit year SBE–FP user fee rate of 2 percent given the impact of user fee rates on market premiums.

Response: The final SBE–FP user fee rate for the 2019 benefit year of 3.0 percent of premiums is based on HHS's calculation of the percent of contract costs of the total FFE functions utilized by SBE–FPs—the costs associated with the information technology, call center infrastructure, and eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs. We have calculated the total costs allocated to SBE–FP functions and enrollment and premium estimates to yield a user fee rate of 3.0 percent for SBE–FP issuers benefiting from functions provided by the Federal platform. We believe issuers offering QHPs through the Federal platform, either the FFEs or SBE–FPs, ought to be charged proportionally for the special benefits provided by the Federal platform. HHS has provided SBE–FPs 2 years to transition to the full rate. Additionally, although HHS reduced its outreach and education costs, we do not charge SBE–FPs for these costs as outreach and education activities are SBE–FPs' responsibility, and therefore the proportion of Federal platform costs associated with SBE–FP functions increased slightly compared to prior years. We also continuously collaborate with our SBE–FP partners to share data within our information disclosure agreements, and welcome continued conversations with SBE–FPs on their data needs.

Comment: Commenters also noted that HHS setting the SBE–FP user fee rate at 3 percent requires State entities to operate a referral hotline, consumer assistance, QHP rate review and certification, legal and finance operations, auditing and other functions with collections based on a State user fee rate of 0.5 percent of premiums, which would not be feasible, or require SBE–FPs to increase assessments on carriers. Commenters noted keeping a lower user fee rate for the SBE–FP model would likely increase States' take-up of these models and enrollment due to the resulting slightly lower increase in premiums.

Response: As we have previously stated, we are not requiring SBE–FPs to allocate a certain share of the State's assessments on various functions, and we are not requiring the SBE–FPs to set the State assessment at any specific rate. If SBE–FP States require more than 0.5 percent of premiums to carry out State functions for the 2019 benefit year, one option for the SBE–FP States could be to assess a higher State charge on issuers, and another option is for the SBE–FP States to assess a charge more broadly on issuers rather than just on issuers offering QHPs on the respective SBE–FPs. We are setting the 2019 SBE–FP user fee rate at 3.0 percent of premiums charged on participating issuers in SBE–FPs to recover the proportion of costs to the Federal government for the benefits associated with SBE–FPs, as required under OMB Circular No. A–25R. We continue to encourage and support States in pursuing the SBE–FP model, in assessing charges on participating issuers, or otherwise, to recover the costs associated with the State's functions and most effectively carry out those functions. We do not believe the total Federal charge assessed on FFE issuers are appropriately compared to the total State and Federal charge assessed on SBE–FP issuers because SBE–FPs provide the benefit of more proximately engaging issuers and consumers.

2. Essential Health Benefits Package

Section 2707(a) of the PHS Act, as added by the PPACA, directs health insurance issuers that offer non-grandfathered health insurance coverage in the individual or small group market to ensure that such coverage includes the EHB package, which is defined under section 1302(a) of the PPACA to include coverage that provides for the EHB defined by the Secretary under section 1302(b) of the PPACA; limits cost sharing in accordance with section 1302(c) of the PPACA; and provides either the bronze, silver, gold, or platinum level of coverage, or is a catastrophic plan under sections 1302(d) and (e) of the PPACA. Section 1302(b) of the PPACA states that the Secretary is to define EHB, except that EHB must include at least the following general categories and the items and services covered within the categories: (1) Ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease

management; and (10) pediatric services, including oral and vision care. Additionally, section 1302(b)(2) of the PPACA states that the Secretary must ensure that the scope of EHB for the 10 EHB categories be equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary. Furthermore, section 1302(b)(2) of the PPACA states, in defining and revising EHB, that the Secretary is to submit a report to the appropriate committees of Congress containing a certification from the CMS Chief Actuary that such EHB are equal in scope to the benefits provided under a typical employer plan. In defining and revising the 10 EHB categories, the Secretary must also provide notice and an opportunity for public comment. Additionally, section 1302(b)(4)(G) and (H) of the PPACA require the Secretary to periodically review and update the definition of EHB and provide a report to Congress and the public that contains assessments related to the need to update the definition of EHB.

Section 1302(b)(4) of the PPACA requires the Secretary, in defining the EHB, to: (1) Ensure that such EHB reflect an appropriate balance among the categories so that benefits are not unduly weighted toward any category; (2) not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life; (3) take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups; (4) ensure the health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life; and (5) provide that a QHP shall not be treated as providing coverage for EHB unless it meets certain requirements for coverage of emergency services.

To implement section 1302(b) of the PPACA, HHS defined EHB based on a benchmark plan approach, which provided at § 156.100 for the States' selection from one of 10 base-benchmark plans, including the largest health plan by enrollment in any of the three largest small group insurance products by enrollment, any of the largest three employee health benefit plan options by enrollment offered and generally available to State employees in the State, any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by aggregate enrollment that is offered to all health-benefits-eligible Federal employees under 5 U.S.C. 8903, or the coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the State. States were required at § 156.110 to supplement their base-benchmark plan from § 156.100 to ensure the 10 EHB categories were being covered to establish the State's EHB-benchmark plan. Section 156.110 also ensures that the EHB-benchmark plan meets the standards of nondiscrimination and balance of benefits, and allows habilitative services to be determined by the State.

We believe that States should have additional choices with respect to benefits and affordable coverage. As such, we proposed to provide States with additional flexibility in their selection of an EHB-benchmark plan for plan year 2019 and later plan years. In addition to granting States more flexibility regulating their markets, we believed these changes would permit States to modify EHB to increase affordability of health insurance in the individual and small group markets beginning in 2019. We proposed that the current EHB-benchmark plan selection would continue to apply for any year for which a State does not select a new EHB-benchmark plan under this proposal.

In the preamble of the proposed rule, we stated that we were considering establishing a Federal default definition of EHB for plan years further in the future that would allow States continued flexibility to adopt their own EHB-benchmark plans, provided they defray costs that exceed the Federal default. We understood that in developing this type of default definition there are trade-offs in adjusting benefits and services. We gave an example of establishing a national benchmark plan standard for prescription drugs that could balance these tradeoffs and provide a consistent prescription drug default standard across States. We solicited initial comments on this type of long-term approach and the trade-offs in adjusting benefits from the current EHBs with a plan to solicit further comments in the future.

Comment: Many commenters requested more detail on a Federal default definition of EHB, with some commenters suggesting the publication of a white paper to discuss such a policy in more detail.

Most commenters opposed a Federal default definition of EHB. Many commenters were concerned that a Federal default definition of EHB would be implemented in the pursuit of seeking arbitrary benefit limits, even at the cost of inferior health outcomes.

Some commenters expressed concern over diminishing the State's flexibility in defining their own EHB, especially since other proposals with regard to EHB concentrated on giving additional flexibility to the States. These commenters also expressed concern over requiring States to defray the costs of benefits in excess of a Federal standard.

Many commenters expressed support for a Federal default EHB definition if such a standard represented a minimum level of benefits required in an EHB-benchmark plan, rather than a maximum level of benefits. Commenters noted that plans should include a wide array of benefits to account for the diverse needs of the population at large. Other commenters supported a Federal default EHB definition to the extent that certain benefits would be included in such a definition.

Most commenters opposed a Federal default definition of EHB as it pertains to a national prescription drug benefit, noting that States and issuers are best positioned to evaluate and respond to prescription drug needs. Many of these commenters expressed concerns similar to those raised regarding a general Federal default EHB definition: Concerns that such a standard would, in the pursuit of arbitrary benefit limits, have a negative impact on health outcomes by inhibiting the availability of needed drugs; establish a maximum level of benefits for EHB-benchmark plans; diminish the States' flexibility to define EHB; and increase the defrayals required by States.

Some commenters noted that a national prescription drug benefit standard would require continuous and frequent updating to account for changes in clinical guidelines and drug innovation. These commenters supported a national prescription drug benefit standard that uses a qualitative approach reliant upon Pharmacy & Therapeutics Committees to respond to such rapid changes, rather than a standard based on providing a minimum number of drugs per category or class.

A few commenters supported a national prescription drug benefit, noting that multi-State issuers face complexity dealing with minimum drug counts which vary widely across EHB-benchmark plans, with no rational medical justification for the variation.

Some commenters expressed concern about the impact of a Federal prescription drug benefit on the ability

of entities to negotiate drug prices. One commenter noted that a Federal default EHB definition for prescription drugs would stifle innovation due to uncertainty over whether a new drug would be covered.

Response: Our intention is to better align medical risk in insurance products by balancing costs to the scope of benefits. We will take these comments under consideration as we consider this policy. In order to avoid market instability and inefficiencies for States that have used the expanded flexibilities regarding EHB that we are finalizing in this rule and issuers in those States, it is our intent that any Federal default standard would not require a State to make immediate changes to its EHB-benchmark plan within 3 years following a State change.

a. State Selection of Benchmark Plan for Plan Years Beginning Prior to January 1, 2020 (§ 156.100)

To reflect the proposed options in § 156.111 for States to adopt new EHB-benchmark plans for plan years 2019 and later, we proposed to make conforming changes to § 156.100 to explicitly state that the selection process in § 156.100 applies only through plan years beginning in 2018, and § 156.111 applies for plan years beginning after 2018. Because we are finalizing § 156.111 to apply for plan years 2020 and later, we are not finalizing these conforming changes as proposed, but are instead making changes to § 156.100 to state that the selection process in § 156.100 applies only through plan years beginning in 2019, and § 156.111 applies for plan years beginning on or after January 1, 2020.

Comment: A few commenters commented on the proposal to make conforming changes to § 156.100 as a result of our proposed changes to § 156.111. These commenters generally did not support the proposed policy of § 156.111 and supported retaining the current benchmark plan options at § 156.100 that provided benchmark plan options at the State level.

Response: Since we are finalizing the new options for a State's EHB-benchmark plan at § 156.111 starting for plan year 2020, we are finalizing conforming changes to § 156.100, to reflect § 156.111.

b. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

i. States' EHB-Benchmark Plan Options (§ 156.111(a))

We proposed to add new § 156.111, which would provide States with the flexibility to update their EHB-benchmark plans more frequently and to select among more options. Specifically, we proposed that a State may change its EHB-benchmark plan by: (1) Selecting the EHB-benchmark plan that another State used for the 2017 plan year[60] under § 156.100 and § 156.110; (2) replacing one or more EHB categories of benefits under § 156.110(a) in its EHB-benchmark plan used for the 2017 plan year with the same categories of benefits from another State's EHB-benchmark plan used for the 2017 plan year under § 156.100 and § 156.110; or (3) otherwise selecting a set of benefits that would become the State's EHB-benchmark plan, provided that the EHB-benchmark plan does not exceed the generosity of the most generous plan among a set of comparison plans. Under this third option, the comparison plans would be the State's EHB-benchmark plan used for the 2017 plan year and the plans described in § 156.100(a)(1) for the 2017 plan year, supplemented as necessary under § 156.110. These plans would include the largest health plan by enrollment in each of the three largest small group insurance products by enrollment from the State's 2017 base-benchmark plan options.[61] Under any of the available three options, we proposed that a State could change its EHB-benchmark plan in any given year, not only in the years that HHS specified. At the same time, this proposed policy would also allow States that prefer to maintain their current EHB-benchmark plans to do so without action.

Option 1: Select Another State's EHB-Benchmark Plan

Under the first option, we proposed that a State be permitted to select one of the EHB-benchmark plans used for the 2017 plan year by another State. We did not propose to change the State mandate policy at § 155.170 under this option. Under this proposed policy, we proposed that benefits mandated by State action prior to or on December 31, 2011 could continue to be considered EHB under § 155.170, and would not require the State to defray the costs. Conversely, if a State selects an EHB-benchmark plan from another State using this option, the selecting State would still be required to defray the cost of any benefits included in that State's EHB-benchmark plan that are benefits mandated by the selecting State after December 31, 2011, and that are subject to defrayal under the current regulations.[62] For example, if State A selects the EHB-benchmark plan of State B, State A would be required to defray the cost of any benefits included in State B's EHB-benchmark plan that are required to be provided by State A's action after December 31, 2011, and that are subject to defrayal under current regulations. We solicited comments on this proposal, including on the application of the State mandate policy under this proposal and on whether other flexibilities are needed by States under this proposed option.

Option 2: Replace Category or Categories From Another State's EHB-Benchmark Plan

Under the second option, we proposed that a State be allowed to partially replace its current EHB-benchmark plan, using EHB-benchmark plans used by other States for the 2017 plan year. Under this option, we proposed that a State may replace any EHB category or categories of benefits in its EHB-benchmark plan from the 10 required EHB categories with the same category or categories of benefits from another State's EHB-benchmark plan used for the 2017 plan year. For example, a State may select the prescription drug coverage from another State's EHB-benchmark plan (which might include a different formulary drug count) and a third State's EHB-benchmark plan hospitalization category. Similar to the first option, we proposed that benefits mandated by State action prior to or on December 31, 2011, could continue to be considered EHB under this proposal in accordance with § 155.170, and would not require the State to defray their costs. However, if a State uses this option to replace one or more categories of its EHB-benchmark plan used for the 2017 plan year with a category or categories of benefits from another State's EHB-benchmark plan used for the 2017 plan year, the selecting State would be required to defray the cost of any benefits included in the categories of benefits from the other State's EHB-benchmark plan that are mandated by the selecting State's action after

[60] The States' EHB-benchmark plans used for the 2017 plan year are based on plans from the 2014 plan year, but we occasionally refer to them as 2017 plans because these plans are applicable as the States' EHB-benchmark plans for plan years beginning in 2017.

[61] The Essential Health Benefits: List of the Largest Three Small Group Products by State for 2017 is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Top3ListFinal-5-19-2015.pdf.* States' EHB-benchmark plans used for the 2017 plan year are able at *https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/Final-List-of-BMPs_4816.pdf.*

[62] Under § 155.170, the State must make payments to defray the cost of additional required benefits either to an enrollee, as defined in § 155.20, or directly to the QHP issuer on behalf of the enrollee.

December 31, 2011 and that are subject to defrayal under current regulations. For example, if State A replaces a category of benefits in its EHB-benchmark plan with a category of benefits from State B's EHB-benchmark plan, State A must defray the cost of any benefits in that category mandated by State A after December 31, 2011 that are included in the replacement category of benefits and that are subject to defrayal under current regulations.

Option 3: Select a Set of Benefits To Become the State's EHB-Benchmark Plan

Lastly, under the third option, we proposed that a State be permitted to select a set of benefits that would become its EHB-benchmark plan using a different process, so long as the new EHB-benchmark plan does not exceed the generosity of the most generous among a set of comparison plans. Under this option, the set of comparison plans would be the State's EHB-benchmark plan used for the 2017 plan year and the plans described in § 156.100(a)(1) that were available as base-benchmark plan options for the 2017 plan year, supplemented as necessary under § 156.110. These plans would include the largest health plan by enrollment in each of the three largest small group insurance products by enrollment from the State's base-benchmark options for the 2017 plan year. We proposed that the State would determine if its proposed EHB-benchmark plan does not exceed the generosity of the most generous of a set of comparison plans using an actuarial certification, developed by an actuary who is a member of American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies. For this actuarial certification, we proposed that the State could determine generosity in the same manner as we would use to measure whether the plan provides benefits that are equal in scope of benefits provided under a typical employer plan, described later in this section.

We also recognized that the increased flexibility offered to States under this proposed option to define an EHB-benchmark plan could allow a State to embed any desired benefit mandate into the EHB-benchmark plan, without any requirement to defray the obligation. For this reason, we proposed to apply the benefit mandate defrayal policy under § 155.170 to this option. Specifically, we proposed that benefits mandated by State action prior to or on December 31, 2011 could continue to be considered EHB under this proposal according to § 155.170, and would not require State defrayal. However, if a State selects its EHB-benchmark plan using this option, the State must continue to defray the cost of any benefits mandated by State action after December 31, 2011 that are subject to defrayal under current regulations. For example, if the State selects a set of benefits to become its EHB-benchmark plan under paragraph (a)(3), any benefits mandated by that State after December 31, 2011 that are subject to defrayal under current regulations would not be considered EHB, and the State would be required to defray the cost of any such benefits included in the State's EHB-benchmark plan under this proposed option.

We solicited comments on all of the proposals, including on whether to allow a State to select its EHB-benchmark plan from any of the 10 previous base-benchmark plan options available to the State or other States under § 156.100, supplemented as necessary under § 156.110, on whether a different approach is needed to defray the cost of any benefits mandated by State action, on whether other flexibilities are needed by States under the proposed options, on our proposed approach to limit a State's new EHB-benchmark plan under Option 3, such that it does not exceed the generosity of the comparison plans, and on whether other options should be provided to States to select their EHB-benchmark plans beyond the three proposed options. We are finalizing these new EHB-benchmark plan options as proposed, with one amendment. As further discussed in the comments and responses below, we are extending the proposed requirements at § 156.111(a)(3)(i) and (ii) that ensure that the State's new EHB-benchmark plan does not exceed the generosity of the most generous among a set of comparison plans to all of the State's options to select a new EHB-benchmark plan at § 156.111(a). We are finalizing these requirements at § 156.111(b)(2)(ii).

Comment: Some commenters supported the proposed EHB-benchmark plan options for States because they offer increased State flexibility through additional options for States. Many commenters did not support the proposed EHB-benchmark plan policy or supported retaining the current policy, and noted that it already allows State flexibility. Many of these commenters were concerned that States would decrease EHB benefits as a result of the proposed policy, or that issuers would not cover benefits that are not EHB. Some commenters were concerned that the options would create a patchwork of benefit designs that could diminish care, increase or shift costs or affect issuer competition.

Other commenters believed that the proposed policy was inconsistent with the statutory requirements that the Secretary define EHB and that the Secretary ensure other EHB consumer protections under section 1302(b)(2), (3), and (4) of the PPACA are incorporated into the definition of EHB. These commenters believed that the Secretary has no authority to delegate defining EHB or its parameters to States or issuers. Commenters also believed that the proposed options allowed States to select an EHB-benchmark plan from among an endless set of options, whereas the prior policy allowed a preset list of 10 plan options per State, with most options being from the State in which the plan was applying. Some commenters also believed that the proposed policy was inconsistent with the statutory requirement that the Secretary update EHB based on gaps in coverage or changes in the evidence identified in the Secretary's report to Congress as established at section 1302(b)(4)(H) of PPACA. Some of these commenters also noted that this report has not been completed.

Response: As described in the EHB Final Rule, we originally established the benchmark plan policy to ensure that EHB is equal to the scope of benefits provided under a typical employer plan and in recognition that the typical employer plans differ by State. Specifically, the Secretary balanced these directives, and minimized market disruption, by directing plans to offer the 10 statutory EHB categories while allowing the State to select the specific details of their EHB coverage from a set of reference plans. Accordingly, States maintained their traditional role in defining the scope of insurance benefits and exercised that authority by selecting a plan that reflects the benefit priorities of that State, within the bounds of the definition of EHB set by the Secretary.[63] This deference to States within the definition established by the Secretary continues under the policies finalized in this rule.

We believe that States should have additional choices with respect to benefits, which may foster innovation in plan design and greater access to coverage, and provide States with a mechanism for affecting affordability. This approach may balance these considerations in manners different from the balance achieved under the previous benchmark plans. The Secretary is defining an expanded set of options from which the State can select

[63] EHB Rule, 78 FR at 12843. February 23, 2013.

its EHB-benchmark plan, allowing the State to select the specific details of that plan. This policy recognizes the need for increased State flexibility beyond that which the original policy allowed.

For this reason, we are finalizing the new options for a State's EHB-benchmark plan, along with additional requirements for the State's selection as detailed later in this preamble. We believe these requirements, when taken together, provide States with significant flexibility while appropriately limiting the range of choices, thereby fulfilling the Secretary's obligation to define EHB. Specifically, the requirement that a State's EHB-benchmark plan provide a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, as defined at § 156.111(b)(2), establishes a minimum scope of benefits that is required to be covered as EHB. Furthermore, the requirement that the EHB-benchmark plan cannot exceed the generosity of the most generous among a set of comparison plans, which are those group market plans that comprise the basis for the scope of benefits under the current definition of EHB, further limits the range of benefits that can be considered EHB. Together with the other requirements specified at § 156.111(b)(2), these requirements provide States with flexibility to adjust their States' EHB-benchmark plan within a limited range.

At the same time, this policy also allows a State to retain its current EHB-benchmark plan. This flexibility was not afforded under the previous policy. In fact, the previous default option, which was the largest plan by enrollment in the largest product by enrollment in the State's small group market, could vary between benchmark plan selection years, creating unnecessary disruption for States that were unable to select a benchmark plan. Under the new policy, these States, as well as States that do not wish to make changes, will not be required to do so, and will not need to take action to prevent the disruption caused by a change to the State's EHB-benchmark plan.

We are not completing the report to Congress and the public on the periodic review of EHB under section 1302(b)(4)(G) of the PPACA at this time. We do not believe that a report on EHB at this time will provide conclusive results on the assessments required under section 1302(b)(4)(G) of the PPACA, as a large portion of plans required to comply with EHB are QHPs offered both on and off of the Exchanges. These QHP markets have seen significant changes from year to year since their inception, with the number of issuers offering plans in each market changing on an annual basis and the number of enrollees in these plans fluctuating. Furthermore, the frequent modifications to EHB policies and other related Federal benefit policies, such as guidance on complying with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and preventive services regulations, have not allowed these plans' benefit structures to stabilize enough for conclusive analysis. Since the PPACA only requires this report to Congress to be conducted periodically, and we do not believe that conducting this report at this time will establish meaningful conclusions, this report will not be completed at this time. We intend to conduct this report once the market has stabilized, which we believe will be furthered by the policy we are finalizing in this rule.

Comment: Many commenters were concerned that the proposed EHB-benchmark plan options would create a race to the bottom among States' scope of benefits for their EHB-benchmark plans. These commenters were especially concerned that these benefit designs would not meet the needs of vulnerable populations, would increase costs to consumers, and would reduce the value of coverage. Some commenters were concerned that benchmark plans selected under one of the first two options would not reflect plans in the State or meet the needs of beneficiaries in that State. Some commenters were concerned that these proposed options discourage States from selecting more generous coverage, with some commenters stating that if the true goal of the policy was to increase State flexibility, the State should also have the option to increase benefits.

Other commenters were concerned that the first two options allow States to pick more generous plans, and some commenters recommended preventing States from being able to select an option without being responsible for the costs of the additional benefits. In general, these commenters were concerned that the proposed policy would allow States to select benchmark plans with more generous State mandates. Other commenters were concerned that there is significant variation in benchmark plan coverage of particular services, and some commenters stated that the goal of allowing State flexibility should be secondary to ensuring comprehensiveness of the benefit package.

Other commenters noted that the second option allows the State to define EHB by selecting the least generous benefits for each category, thus creating a standard that does not resemble any existing plan in the market today. Commenters were similarly concerned that the third option could allow a State to greatly reduce the generosity of coverage, even though the definition would still require the coverage of the 10 EHB categories. Some commenters were concerned that the third option was too broad and did not ensure consumer protections to ensure the comprehensive scope of benefits.

Response: We are not persuaded that the new options will create a race for States to establish the least generous plan possible because all States' EHB-benchmark plans will be required to include coverage for all 10 EHB categories of benefits, and the State will be required to confirm its EHB-benchmark plan includes coverage for each EHB category in accordance with § 156.111(e)(1). Section 156.111(e)(1) also requires States to confirm that its new EHB-benchmark plan meets the applicable requirements of § 156.111(b) on scope of benefits, including that the State's EHB-benchmark plan provide a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan in accordance with § 156.111(e)(2).[64] Through those requirements, the options at § 156.111(a) do not allow a State to substantially reduce the level of coverage, and instead allow a State the option to adjust its EHB-benchmark

[64] We are also retaining the current issuer requirements related to EHB at §§ 156.115, 156.122, and 156.125 and those requirements would continue to apply to all plans subject to the EHB requirements. This includes 45 CFR 156.122(a)(1) that establishes that, generally, a health plan does not provide EHB unless it covers at least the greater of: (1) One drug in every USP category and class; or (2) the same number of prescription drugs in each category and class as the EHB-benchmark plan. Under the current version of the USP Medicare Model Guidelines (MMG) drug classification system used for the EHB drug count at § 156.122(a)(1), this proposal means that all plans required to comply with EHB will continue to have to cover at least one drug in the Anti-Addiction/Substance Abuse Treatment Agents (Opioid Reversal Agent) class. Naloxone is currently the only active ingredient in the Opioid Reversal Agent class, and as a result all plans required to comply with EHB would be required to continue to cover at least one form of naloxone under this proposed policy. This was previously addressed in the 2018 Letter to Issuers in the Federally-facilitated Marketplaces available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2018-Letter-to-Issuers-in-the-Federally-facilitated-Marketplaces-and-February-17-Addendum.pdf.*

plan to use benefit structures that have worked well in other States or other parts of the employer markets, or otherwise innovate benefits within the range of plans in the employer market. Because each State has different market conditions and demographic distributions, a plan that may be the least generous plan in one State may not be the least generous plan in another State, and for that reason, we are not concerned that this policy is going to create a race to establish the least generous plan.

In short, this flexibility established under § 156.111(a) is not intended to reduce benefits, but to allow for more innovative benefits within the current benefit requirements. This means that a State's EHB-benchmark plan may not have the exact same benefits and limits as the typical employer plan the State identifies under this policy, but this policy will still result in the State's EHB-benchmark plan providing a scope of benefits equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, satisfying the Secretary's obligations at section 1302(b) of the PPACA. Furthermore, as described later in this rule, we are finalizing a definition of a typical employer plan that requires the plan have enrollment and be sold in the State. This definition ensures that regardless of the benchmark plan option selected by the State under this rule, that benchmark plan will be at least equal to the scope of benefits to a popular employer plan that was previously offered in the State's employer plan market.

Furthermore, we encourage States to select EHB-benchmark plans that foster innovation in plan design that would provide greater access to coverage that would ultimately improve affordability. As discussed in the proposed rule, in addition to granting States more flexibility in regulating their markets, one of the goals with this policy was to permit States to modify EHB to increase affordability of health insurance in the individual and small group markets.[65] As we also note in our discussion of benefits mandated by State action at § 155.170, we want to ensure that States do not select EHB in a manner that decreases affordability of coverage. Therefore, in response to commenters' concerns about ensuring that the options under § 156.111(a) do not undermine the goal of affordability, we are incorporating into the regulation protections to ensure that a State's EHB-benchmark plan selections take into account affordability of coverage, by applying the generosity test proposed in connection with the third option to all three EHB-benchmark plan selection options for States. Accordingly, § 156.111(b)(2)(ii) provides that a State may not select a new EHB-benchmark plan that exceeds the most generous among a set of comparison plans, no matter the option used to generate the EHB-benchmark plan. These comparison plans include the State's EHB-benchmark plan used for the 2017 plan year and the plans described in § 156.100(a)(1) for the 2017 plan year, supplemented as necessary under § 156.110.[66] We recognize that it may be possible for a State's EHB-benchmark plan to provide a scope of benefits that is equal to (or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a)) the scope of benefits provided under a typical employer plan at § 156.111(b)(2)(i), and not meet the generosity standard at § 156.111(b)(2)(ii) (for example, a proposed EHB-benchmark plan could satisfy the typical employer plan requirement but exceed the generosity standard because of the way supplementation was performed). However, we believe that by extending this generosity limit to all selection options, we are minimizing the opportunity for a State to select EHB in a manner that would make coverage unaffordable for patients and increase Federal costs, while still helping to ensure that States are ensuring that benefits are equal to the scope of benefits provided under a typical employer plan.

Comment: Some commenters were concerned that a State would have difficulty knowing what another State's EHB-benchmark plan was covering, because the benefits or benchmark plan documentation were not broken into separate EHB categories. Some commenters were generally concerned about using the 2017 EHB-benchmark plans. These commenters noted that States are only supplementing categories of benefits in those plans when those categories are missing and are not considering the scope of benefits within the category, leading to inadequate coverage. Other commenters wanted to understand how supplementation would work under the options.

Response: Additional supplementation of the EHB-benchmark plans generally should not be required under the three State EHB-benchmark plan selection options being finalized at § 156.111(a). For the first option at § 156.111(a)(1), the selecting State would be selecting another State's EHB-benchmark plan, which already would be supplemented, as necessary.[67] For the second option at § 156.111(a)(2), the State would replace a category or categories of benefit from its current EHB-benchmark plan with another State's EHB-benchmark plan's category or categories of benefits, which already would have been supplemented, if necessary, by that other State.

A State using the third option will need to ensure that its EHB-benchmark plan satisfies the requirements being finalized at § 156.111(b), such as the requirements to cover items and services in each of the ten statutory categories of EHB; to not have benefits unduly weighted towards any of those categories of benefits; and to provide a scope of benefits equal to (or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a)), the scope of benefits provided under a typical employer plan. Since States have been supplementing their EHB-benchmark plans since the inception of the EHB policy, we expect States to be familiar with categorizing benefits.

Comment: Various commenters supported coverage of specific services within an EHB category, with some commenters noting that many of the services that might be considered for reduction are only a small portion of spending. They stated that not covering these services would not meaningfully reduce premiums and would increase or shift costs for the services for the consumers who need them. Other commenters noted that all of the options are linked in part to the 2017 EHB-benchmark plans (including the generosity standard under Option 3), and that these are in fact 2014 plans. Certain commenters were concerned

[65] 82 FR at 51102.

[66] The actual number of comparison plans for each State depends on the State's EHB-benchmark plan for 2017. Most States will only have three comparison plans as the State's EHB-benchmark plan for 2017 is a plan within the options at § 156.100(a)(1). However, a few States will have four comparison plans as the State's EHB-benchmark plan for 2017 is not a plan within the options at § 156.100(a)(1). The list of plan options at § 156.100(a)(1) for each State for 2017 is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Top3ListFinal-5-19-2015.pdf.* Also, the States' EHB-benchmark plans used for the 2017 plan year are available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/Final-List-of-BMPs_4816.pdf.*

[67] Information on whether the State supplemented its EHB-benchmark plan for 2017 is available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/Final-List-of-BMPs_4816.pdf.*

that these 2014 plans do not comply with new requirements, such as the applicability of requirements under MHPAEA or noted that using 2014 plans in the long term means that EHB would still be linked to 2014 plans. Comments varied on whether States that are selecting an EHB-benchmark plan should be allowed to select from any States' previous EHB-benchmark plans for options § 156.111(a)(1) or (2). A few commenters recommended that HHS give States additional technical assistance. For example, one commenter sought clarification on which State entity would be authorized to select the State's EHB-benchmark plan. Certain commenters also had concerns about provider discrimination under the proposed policy.

Response: Because § 156.111 continues to define EHB based on a ''benchmark plan'' approach, we are continuing the policy of not requiring that a State's EHB-benchmark plan cover a specific service or services or use particular providers. We are limiting the policy to the 2017 EHB-benchmark plans under Options 1 and 2 at § 156.111(a)(1) and (2) to ensure that the set of plans available for States to select from under Option 1 and 2 are clearly defined and reflect an EHB-benchmark plan that was used by another State. We believe that this policy balances providing flexibility to States to select from more options for their EHB-benchmark plans while at the same time providing simplification of choice within a defined set of plan options. Furthermore, this policy will not overly limit State flexibility, as the third option would permit a State to select from any of the other 10 previous base-benchmark plan options. While the 2017 EHB-benchmark plans and the benchmark plans selected by States under § 156.111(a)(3) may not comply with all of the market reforms and consumer protections applicable to plans offered in the individual and small group markets, this is not a departure from the benchmarks that have been used to date. We reiterate the policy that non-grandfathered insurance plans in the individual and small group markets that are required to comply with EHB must not only provide benefits that are substantially equal to the EHB-benchmark plan, but must also comply with all Federal requirements applicable to plans offered in those markets, such as those benefit requirements at §§ 156.115, 156.122, 156.125, and 156.130(g).

We also recognize that States have different processes for selecting a benchmark plan and as a result, the State needs discretion in determining what entity has the authority to select the State's EHB-benchmark plan. We therefore will not dictate which State entity must act to select a State's EHB-benchmark plan, but we may consider providing States with additional technical assistance to aid in their selection under the policy finalized in this rule.

Comment: Many commenters were concerned about the impact of the proposed policy on the determination of which benefits are subject to the prohibition of annual and lifetime dollar limits in section 2711 of the PHS Act, as added by the PPACA, and the annual limitation on cost sharing at section 1302(c) of the PPACA (which is incorporated into section 2707(b) of the PHS Act). Some commenters were particularly concerned about the impact of this policy on markets beyond the Exchanges, particularly the large group market and self-insured group health plans. These plans are not required to provide coverage of EHB but must use a definition of EHB to determine which benefits apply to the prohibition of annual and lifetime dollar limits and the annual limitation on cost sharing. These commenters were generally concerned about increased or shifting costs to consumers for benefits that are no longer EHB, particularly for vulnerable populations. Some commenters were concerned that since large group market and self-insured group health plans could use any State's definition of EHB for purposes of the annual and lifetime dollar limit prohibition and the annual limitation on cost sharing, any State's definition could have the potential to impact plans nationwide. Other commenters wanted additional information and evaluation of the impact on how the change in definition would be implemented.

Response: As discussed in more detail earlier in this section, the flexibility established under § 156.111(a) is not intended to reduce benefits, but to allow for more innovative benefits within the current benefit requirements. This means that a State's EHB-benchmark plan may not have the exact same benefits and limits as the typical employer plan the State identifies under this policy, but this policy will still result in the State's EHB-benchmark plan providing a scope of benefits that is equal to, or greater than, the scope of benefits provided under a typical employer plan in accordance with § 156.111(b)(2)(i), satisfying the Secretary's obligations at section 1302(b) of the PPACA. Accordingly, we do not expect that there will be a substantial change to the scope of the protections afforded under the annual and lifetime dollar limit prohibition or the annual limitation on cost sharing.

ii. The Requirements for States' EHB-Benchmark Plans (§ 156.111(b) Through (d))

Under the proposed options for States to select a new EHB-benchmark plan, we proposed that a State's EHB-benchmark plan must meet certain requirements established under the PPACA with regard to EHB coverage, scope of benefits, and notice and opportunity for public comment. First, under paragraph (b)(1), we proposed to require that the State's EHB-benchmark plan provide an appropriate balance of coverage for the 10 EHB categories of benefits as established at § 156.110(a) and under section 1302(b)(1) of the PPACA. Second, we proposed at paragraph (b)(2) to define requirements regarding the scope of benefits that must be provided by a State's EHB-benchmark plan. Specifically, we proposed at paragraph (b)(2)(i) that the State's EHB-benchmark plan must be equal in scope of benefits to what is provided under a typical employer plan. This proposed requirement reflects section 1302(b)(2) of the PPACA, which requires the Secretary to ensure that the scope of the EHB is equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary. We proposed to define a typical employer plan as an employer plan within a product (as these terms are defined in § 144.103 of this subchapter) with substantial enrollment in the product of at least 5,000 enrollees sold in the small group or large group market, in one or more States, or a self-insured group health plan with substantial enrollment of at least 5,000 enrollees in one or more States. We sought comment on many parts of this definition, including:

- Whether the definition of a typical employer plan should reflect in substantial part a plan that would be typical in the State in question;
- Whether an appropriate way to measure typicality in that case would be to provide that the typical employer plan be defined to also have at least 100 enrollees enrolled in that plan or product in the applicable State;
- Whether typicality should be defined in other ways, including whether it should be based upon the State's 10 base-benchmark plan options for plan year 2017, supplemented as required to become the State's EHB-benchmark plan under § 156.110;
- Whether the definition of a typical employer plan for this purpose should be limited to plans that already cover all 10 EHB categories;

• Whether the proposed typical employer plan definition should exclude self-insured plans, since States may not have the ability to obtain the required information on those plans; and

• Whether we should provide additional guidance or requirements for the definition of a typical employer plan, such as requiring that the plan selected as a typical employer plan be from a recent year after December 31, 2013, requiring that the plan provide minimum value, or requiring that the plan selected as a typical employer plan not be an indemnity plan or an account-based plan like a health reimbursement arrangement.

Given that the proposed definition of a typical employer plan was a plan with enrollment of at least 5,000 enrollees in one or more States, we believed that the State's option to select another State's EHB-benchmark plan at proposed § 156.111(a)(1) would automatically meet the typical employer plan requirement because each of the available options is an employer plan that had substantial enrollment.

We also solicited comment on whether actuaries could develop a standard of practice for a benefit comparison calculation to determine that a plan is equal to the scope of benefits provided under a typical employer plan that could also apply to determine that a State's EHB-benchmark plan does not exceed the generosity of the most generous plan in accordance with the third option under proposed § 156.111(a)(3). We specifically sought comment on our draft example of an acceptable methodology for comparing benefits of a State's EHB-benchmark plan selection to the benefits of a typical employer plan.[68]

In addition to meeting the typical employer plan requirements, we proposed at paragraph (b)(2)(ii) that the State's EHB-benchmark plan must also not have benefits unduly weighted towards any of the categories of benefits at § 156.110(a) as established under section 1302(b)(4)(A) of the PPACA. Furthermore, we proposed at paragraph (b)(2)(iii) that the State's EHB-benchmark plan must provide benefits for diverse segments of the population, including women, children, persons with disabilities, and other groups as established under section 1302(b)(4)(C) of the PPACA.

At paragraph (c), we proposed that the State must provide reasonable public notice and an opportunity for public comment on the State's selection of an EHB-benchmark plan. We proposed that this process would apply whenever a State changes its EHB-benchmark plan in accordance with proposed § 156.111(a).

Lastly, we proposed at paragraph (d) that a State must notify HHS of the selection of a new EHB-benchmark plan by a date to be determined by HHS for each applicable plan year. We also proposed that if the State does not make a selection by the annual selection date, the State's EHB-benchmark plan for the applicable plan year would be that State's EHB-benchmark plan applicable for the prior plan year. Taken together, these proposed requirements were intended to align with statutory requirements. We affirmed that §§ 156.115, 156.122, and 156.125 would continue to apply to all plans subject to the EHB requirements.

We are finalizing the requirements for a State's EHB-benchmark plan with certain amendments to: (1) Clarify that the State's EHB-benchmark must provide coverage of items and services for at least the 10 EHB categories; (2) add a codification of the currently applicable requirement at § 156.110(d) that the State's EHB-benchmark plans must not include discriminatory benefit designs that contravene the non-discrimination standards defined in § 156.125; (3) modify the definition of a typical employer plan; (4) add a requirement that the State must post a notice of its opportunity for public comment with associated information on a relevant State website; (5) provide that any State EHB-benchmark plan may be no more generous than the most generous among a set of comparison plans, as described above; and (6) codify in regulation text the proposed standard in the preamble of the proposed rule that if a State's benchmark plan selection does not meet the requirements of this section and section 1302 of the PPACA, the State's EHB-benchmark plan will be the State's EHB-benchmark plan applicable for the prior year, as further described under the data collection section below. To reflect the application of the generosity standard to all three options under this regulation, we moved that provision from § 156.111(a)(3) to § 156.111(b)(2), and have renumbered parts of § 156.111(b)(2) for clarity.

Comment: Many commenters stated that the definition of EHB provides important protection to consumers, particularly with regard to various populations. Some commenters appreciated the codification of certain EHB protections under section 1302(b) of the PPACA into the regulation text, with some requesting the non-discrimination provisions from section 1302(b) of the PPACA be included, too. Some commenters wanted strong Federal enforcement of EHB requirements, such as non-discrimination. Some commenters believed that the standards were too vague or wanted additional guardrails on States' EHB-benchmark plans. A few commenters wanted certain clarifications to § 156.111(b)(1), such as the inclusion of items and services or on requiring coverage of the 10 EHB categories.

Response: In the proposed rule, we did not propose to eliminate the EHB-benchmark plan standards under § 156.110. However, we recognize based on comments that the applicability of that section to benchmark plans selected under the proposed § 156.111 was not as clear as it could have been. Therefore, in response to commenters, we are finalizing § 156.111(b) with certain amendments that align with the statute and that clarify the applicability of EHB-benchmark plan standards. We are amending § 156.111(b)(1) to more explicitly state that the EHB-benchmark plan must not only provide an appropriate balance of coverage of the 10 statutory categories of EHB, but also cover items and services in all 10 categories.

We are also adding a new § 156.111(b)(2)(v) to codify the continuing applicability of the currently applicable benchmark plan non-discrimination provisions under § 156.110(d) to the EHB-benchmark plan selection options under § 156.111(a). Specifically, a State's EHB-benchmark plan may not violate the non-discrimination standards defined in § 156.125, which reflects the non-discrimination provisions of section 1302(b)(4) of the PPACA.

Comment: Many commenters opposed allowing States to annually update their EHB-benchmark plans. These commenters had a variety of concerns about annual updates to the benchmark plans, such as annual updating would be administratively and financially burdensome to issuers, confusing for consumers, lack predictability, or would create instability that would not allow issuers to assess the effectiveness of previous changes before new changes are implemented. Some commenters recommended limiting the changes to every few years, with some supporting every 3 years, which aligns with the

[68] The *Draft Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection to Benefits of a Typical Employer Plan As Proposed under the HHS Notice of Benefit and Payment Parameters for 2019 (CMS–9930–F)* is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Example-Acceptable-Methodology-States-EHB.pdf.*

frequency with which the benchmark plans have previously been updated. Some commenters recommended timeframes for the State's annual submission process, such as requiring the EHB-benchmark plans to be finalized 18 months prior to the benefit year, to help ensure that issuers have sufficient time to design products in advance of the filing deadlines for the upcoming benefit year.

Response: As discussed in the proposed rule, we recognize the burden on States and issuers of making changes to a State's EHB-benchmark plan. Specifically, we anticipated most States would need to invest resources to analyze the three new EHB-benchmark plan selection options to make an informed selection, even if a State defaults. We also anticipated that issuers offering plans that provide EHB would incur additional administrative costs associated with designing plans compliant with the State's newly selected EHB-benchmark plan.[69] Because of the level of effort needed by the State and its issuers to make changes to a State's EHB-benchmark plan, we believe that in only very limited cases will a State choose to make EHB-benchmark plan changes on an annual basis. We believe that if a State does decide to make changes annually, there may be a specific reason for needing an annual change such as for a medical innovation where such benefits would outweigh any potential for consumer confusion. We also do not believe that such changes would rise to the level of creating market instability. The purpose of this policy is to allow for State flexibility in selecting an EHB-benchmark plan, and we believe it is important for States to retain the flexibility to choose when the State wants to make changes to its EHB-benchmark plan. Therefore, we are finalizing the policy as proposed.

As described in the next section, we are finalizing the 2020 deadline for submission of a State's EHB-benchmark plan under § 156.111(a). For plan years after 2020, we intend to announce the annual EHB-benchmark plan selection deadline to States in the annual notice of benefits and payment parameters. Because we expect that the number of submissions for each plan year will vary, we will not be providing a specific date as to when the State's EHB-benchmark plans for a given plan year will be finalized.

Comment: Many commenters opposed allowing the definition of typical employer plan to include self-insured plans, as these plans can have unique benefit designs, and are not directly regulated by States, and because it would be difficult to obtain plan information for such plans. Some commenters stated that the lack of specificity in the definition of a typical employer plan could allow rare, outlier plans with extremely limited coverage to become the typical employer plan, or they requested that there be additional requirements on the typical employer plan to prevent outlier plans from being the typical employer plan. Commenters were concerned that the definition could jeopardize adequate coverage of the 10 EHB categories, lowering the threshold for minimum coverage, or allowing insurers to offer plans with less generous benefits, weakening the PPACA protections for individuals with disabilities and complex medical needs.

Some commenters were particularly concerned that the policy in the proposed rule generally focused on using the definition of EHB to create a ceiling for the scope of benefits. They expressed concern that the generosity standard limits the scope of benefits to certain previous benchmark plan options, instead of providing the floor for the scope of benefits, as they stated PPACA intended the definition of EHB to be. These commenters were concerned that decreased benefits would result in high costs for consumers to access those services.

Some commenters wanted more specificity in the definition of typical employer plan, such as wanting the plan to be specific to the State to ensure compatibility in the State or meet State requirements, be required to cover all 10 EHB categories or minimum benefit standards, be from a recent plan year, constitute MEC, provide minimum value (or some other actuarial value standard), not be an account-based plan, not be a preventive-services-only plan or an excepted benefit plan or not be an indemnity plan. Some commenters supported the definition of a typical employer plan for its flexibility or supported aspects of the proposed definition. Another commenter noted that if a State-specific enrollment requirement is added, current EHB-benchmark plans under the first option may not automatically meet the definition.

Commenters recommended different enrollment thresholds for the typical employer plan, with some commenters noting that substantial enrollment varies by State or the lack of justification for the 5,000 enrollee threshold. Other commenters believed that the proposed policy disregarded the concept of typicality as being the scope of coverage typically seen in employer-based plans or did not believe enrollment should be an indicator for typicality (as typicality is about comparability and enrollment is about size).

Response: We agree with commenters that the definition of EHB should establish a minimum level of benefits. In response to commenters' concerns with the proposed definition of typical employer plan, we are finalizing two sets of typical employer plans from which a State may choose for purposes of ensuring a minimum scope of benefits for the State's EHB-benchmark plan, which establishes the State's EHB definition.

First, we are finalizing that the typical employer plan may be one of the selecting State's 10 base-benchmark plan options established at § 156.100 from which the State could select for the 2017 plan year. This definition, which allows the selecting State to continue to select from its previous options, will allow a selecting State to modify its previous base-benchmark plan options to innovate those benefits to better meet the needs of consumers in its market.

Second, we are finalizing that a typical employer plan also may be the largest health insurance plan by enrollment in any of the five largest large group health insurance products by enrollment in the selecting State, as product and plan are defined at § 144.103, provided that: (1) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products by enrollment in the selecting State; (2) the plan provides minimum value, as defined under § 156.145; (3) the benefits are not excepted benefits, as established under § 146.145(b) and § 148.220; and (4) the benefits in the plan are from a plan year beginning after December 31, 2013.

For purposes of this definition, we are applying the Federal definitions of plan and product at § 144.103.[70] Under these definitions, the product comprises all plans offered with the same covered benefits and as a result, each plan within a product must have the same benefit package. To ensure that these plans are typical within the selecting State, the determination of each product's enrollment numbers is based on enrollment in the selecting State.

[69] 82 FR at 51131.

[70] Section 144.103 defines ''product'' as ''a discrete package of health insurance coverage benefits that are offered using a particular product network type (such as health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity) within a service area'' and a plan as ''with respect to a product, the pairing of the health insurance coverage benefits under the product with a particular cost-sharing structure, provider network, and service area.''

Also, to ensure that none of these products are outliers within the State, only plans from products that have at least 10 percent of the total enrollment of the five largest large group health insurance products can be selected. For example, if a selecting State's three largest large group health insurance products under the second definition at § 156.111(b)(2)(ii) have 92 percent of the enrollment in the selecting State among the five largest large group health insurance products in the State, the fourth and fifth largest large group health insurance products in the selecting State will not have at least 10 percent of the enrollment and therefore, will not be an option under the second prong of the typical employer plan definition. The use of enrollment size in defining the typical employer plan aligns with the previous policy where the base-benchmark plan options were also determined based on the enrollment in those markets. Furthermore, by using the largest products by enrollment in the selecting State, rather than on a specified enrollment size, we ensure that any variation in population size by the selecting State is taken into account. We believe this second prong of the definition provides States with important additional flexibility, as it expands the comparison options available to States when comparing their selected EHB-benchmark plan to a typical employer plan, while simultaneously ensuring the statutory requirement that the definition of EHB be equal in scope to a typical employer plan is met.

We agree with commenters that self-insured plans have a significantly greater likelihood of being plans with atypical benefit designs. Therefore, this definition for typical employer plan does not include self-insured plans, including health reimbursement arrangements. We also recognize that States would have challenges obtaining information about these other types of plans, especially at the level of detail needed for the plan to be used as a comparison to the State's EHB-benchmark plan. To limit the burden on States to determine which plans in the State would be included in the second set of plans, we are limiting the second set under the definition of typical employer plan to large group market health insurance plans and products.

In response to commenters who recommended that the typical employer plan be required to provide minimum value (MV), we are also finalizing as part of the second prong of the definition of the typical employer plan that the plan must meet MV requirements under § 156.145. Under § 156.145, an employer-sponsored plan provides minimum value only if the percentage of the total allowed costs of benefits provided under the plan is greater than or equal to 60 percent, and the benefits under the plan must include substantial coverage of inpatient hospital services and physician services, characteristics that we believe are reflective of typical employer plans. For example, by requiring the typical employer plan meet MV, outlier plans, such as preventive-services-only plans, which do not provide substantial coverage of inpatient hospital and physician services in accordance with the MV requirement, could not satisfy the second definition of typical employer plan.

To further respond to comments recommending that we ensure that outlier plans are excluded from the definition of typical employer plan, we are finalizing as part of the second prong of the definition a requirement that the plan's benefits are not excepted benefits, as defined under § 146.145(b), and § 148.220. For example, a worker's compensation plan would not meet the second prong of the definition of a typical employer plan. This requirement specifically ensures that the typical employer plan is a major medical plan. Lastly, we are requiring that the benefits in the plan are from a plan year beginning after December 31, 2013. This requirement is consistent with the options under the first prong of the typical employer plan definition, which references plans originally offered in 2014.

In applying the typical employer plan definition, we recognize that States may find that the plans that meet the definition of a typical employer plan may not provide coverage for items and services within each EHB category at § 156.110(a). Therefore, we are finalizing that the State's EHB-benchmark plan must provide a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan. The purpose of this approach is to permit States' EHB-benchmark plans' scope of benefits not to be equal to the benefits under the typical employer plan definition, only by exceeding the scope of benefits provided by the typical employer plan, and only if necessary to ensure that all EHB categories of benefits are being covered. We believe that these requirements, when taken together, ensure outlier plans are excluded from the definition of a typical employer plan, respond to commenters' concerns regarding the risk that the definition of typical employer plan would include atypical plans and ensure that the requirement for the EHB-benchmark plans' scope of benefits to be equal to that of a typical employer plan can account for benefits within each EHB category at § 156.110(a).

Comment: Some commenters believed that the statute requires that the scope of benefits for the typical employer plan be informed by the Department of Labor report [71] required under section 1302(b)(2)(A) of PPACA. These commenters did not believe that the proposed typical employer plan definition was informed by the 2011 DOL report and were concerned that defining the typical employer plan using enrollment instead of typicality of benefits allows skimpier benefits, which would have a detrimental effect on the most vulnerable enrollees in a way that contravenes the PPACA requirement and implicates the Americans with Disabilities Act. Some commenters were particularly concerned about the impact of the proposed typical employer plan definition under the third option and some commenters expressed concern about the potential scope of coverage under plans that meet the proposed definition. Some commenters expressed concern about coverage of benefits for specific groups, such as those with opioid use disorders.

Response: As required by section 1302(b)(2)(A) of the PPACA, the Department of Labor conducted a survey of employer-sponsored coverage and published a report on the survey on April 15, 2011. In determining what constitutes a typical employer plan, HHS reviewed and considered the findings of this survey. As discussed in more detail earlier in this section, the flexibility established under § 156.111(a) is not intended to reduce benefits, but to allow for more innovative benefits within the current benefit requirements. Similarly, with regard to comparing the scope of benefits of an EHB-benchmark plan to a typical employer plan, we note that the scope of benefits refers to the overall extent of benefits covered, not to the inclusion of any particular benefits. A State's EHB-benchmark plan is not required to cover a particular benefit because that benefit is part of the typical employer plan the State uses to assess the scope of benefits in its EHB-benchmark plan. Rather, the particular

[71] Selected Medical Benefits: A Report from the Department of Labor to the Department of Health and Human Services. April 15, 2011. *https://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf.*

benefits and limitations in a State's EHB-benchmark plan are established through one of the options defined in §§ 156.100, 156.110 or 156.111 and the resulting EHB-benchmark plan provides a scope of benefits that is equal to, or greater than the scope of benefits that typical employer plan, as explained earlier in this preamble.

We encourage States to consider, as they select their EHB-benchmark plans, the potential impact on vulnerable populations, and the need to educate consumers on benefit design changes. Specifically, as States work to address the opioid crisis, we urge States to consider whether and how selecting a new EHB-benchmark plan could help address the crisis in their State.

Comment: Commenters generally supported requiring States to provide public notice and an opportunity for public comment on its selection of an EHB-benchmark plan, with some commenters supporting State flexibility to determine the process. Most commenters, on the other hand, wanted minimum or standardized requirements for the public comment process, such as requiring the solicitation of input from certain groups, a public hearing, a comment period of 30 days or 60 days, the posting of usable and understandable data, analysis and plan documents (such as the documentation to be submitted to HHS under § 156.111(e)), posting of any changes, a requirement that the State submit documentation on its public hearing process to HHS, or some combination of these standards. These commenters typically wanted a transparent process to ensure meaningful and equal participation of consumers, or wanted to reduce the burden of having a different process for each State. One commenter wanted the regulation to at least reference the State's applicable public comment period under the State's administrative procedure act or department of insurance rules while another was concerned that the rule assumes that a State has in place a reasonable public comment process. Some commenters supported requiring the State to post public notice while other comments wanted a process to identify inadequacies or appeal a State's decision.

Response: We agree with commenters that the State public notice and comment period is important for transparency to allow consumers to provide feedback on the States' proposed changes to their EHB-benchmark plans. However, we believe that States have varying processes for soliciting and receiving comments and may have used varying processes previously to provide public notice and an opportunity for public comment on their EHB-benchmark plan selections.

Therefore, in an effort to retain State flexibility under this requirement, with one exception, we are finalizing a policy under which States must provide reasonable public notice and opportunity for public comment, but will look to States to reasonably interpret that requirement. In response to comments, we are finalizing a requirement that the State, regardless of the public comment process it uses to select its EHB-benchmark plan, must post a notice on a relevant State website regarding the opportunity for public comment with associated information.

For States that do not have a public notice and comment process for these purposes, these States should consider using a similar process for public comment to the one established at § 155.1312(a)–(c). We also remind States that any public participation processes must continue to comply with applicable Federal civil rights laws, including those that require covered entities to provide meaningful access for individuals with limited English proficiency, and those that require effective communications for individuals with disabilities, including web accessibility requirements. The public notice process at § 156.111(c) applies whenever a State changes its EHB-benchmark plan in accordance with § 156.111(a).

iii. Data Collection for State's EHB-Benchmark Plans for 2020 Plan Year and Later (§ 156.111(e))

We proposed data collection requirements at § 156.111(e) for a State that opts to select a new EHB-benchmark plan under § 156.111(a) in any given year, beginning with the 2019 plan year. We proposed that a State must submit documents in a format and manner specified by HHS by a date determined by HHS and proposed four areas of documentation. First, at paragraph (e)(1), we proposed to require documentation that would confirm that the State's EHB-benchmark plan complies with the requirements under proposed § 156.111(a), (b) and (c), which includes the requirement that the 10 EHB categories of benefits are covered under the State's EHB-benchmark plan. This documentation would also include information on which selection option under proposed § 156.111(a) the State is using, including whether the State is using another State's EHB-benchmark plan.

Second, in paragraph (e)(2), we proposed, for a State selecting an EHB-benchmark plan under § 156.111(a)(2) or (3), that the State's documentation must include an actuarial certification and an associated actuarial report from an actuary, who is a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies, affirming that the State's EHB-benchmark plan is equal in scope of benefits provided under a typical employer plan. We proposed that if the State is selecting its EHB-benchmark plan using § 156.111(a)(3), which allows the State considerable flexibility to otherwise select a set of benefits that would become its EHB-benchmark plan, that the actuarial certification and associated report would also affirm that the new EHB-benchmark plan does not exceed the generosity of the most generous among the set of comparison plans specified in paragraph (a)(3). For the actuarial certification, we proposed that these documents, in accordance with generally accepted actuarial principles and methodologies, would include complying with all applicable Actuarial Standards of Practice (ASOP) (including but not limited to ASOP 41 on actuarial communications). We also sought comment on a draft methodology for comparing benefits of a State's EHB-benchmark plan selection to the benefits of a typical employer plan for the actuarial certification and associated actuarial report [72] and on whether the draft methodology should be the required approach for the State's actuarial certification and associated actuarial report.

Third, we proposed at paragraph (e)(3) that the State would be required to submit an EHB-benchmark plan document that reflects the benefits and limitations in the benchmark plan, including the medical management requirements, a schedule of benefits and, if the State is selecting its EHB-benchmark plan using the option in paragraph (a)(3), a formulary drug list in a format and manner specified by HHS similar to current § 156.120. For a State that chooses an EHB-benchmark plan under proposed § 156.111(a)(1), the State may submit the plan document from the other State's EHB-benchmark plan used for the 2017 plan year to fulfill this proposed requirement. For a State that selects an EHB-benchmark plan under proposed § 156.111(a)(2), the

[72] The *Draft Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection to Benefits of a Typical Employer Plan As Proposed under the HHS Notice of Benefit and Payment Parameters for 2019 (CMS–9930–F)* is available on CCIIO's Regulation and Guidance web page at *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.html.*

State could create a combined plan document by assembling parts of the plan documents from the other State's or States' benchmark plan documents. We acknowledged that States may need to make conforming edits in the other States' plan documents to align language and terminology. For a State that chooses the option proposed at § 156.111(a)(3), the State may need to develop a plan document. Additionally, under proposed § 156.111(e)(3), if the State is selecting its EHB-benchmark plan using the option in § 156.111(a)(3), we proposed that the State must also include a formulary drug list for the State's EHB-benchmark plan in a format and manner specified by HHS. We also proposed that for a benefit, such as the pediatric dental benefit, that is defined by another program under the State's EHB-benchmark plan, the State may submit a separate document that reflects the benefits and limitations, including the medical management requirements and a schedule of benefits comparable to how States that defined their dental coverage using their State's CHIP programs have done previously. Otherwise, regardless of which option the State is using to select a new EHB-benchmark plan, the State would be expected to submit one comprehensive plan document for the entire State's EHB-benchmark plan selection.

Lastly, we proposed under paragraph (e)(4) to require the State to submit documentation specified by HHS, which is necessary to operationalize the State's EHB-benchmark plan. This documentation would be used to provide public resources on a State's EHB-benchmark plan and support related templates and tools. We proposed that this documentation would include a complete and accurate EHB summary chart that reflects the State's EHB-benchmark plan and aligns with the documentation that we currently make publicly available on a State's EHB-benchmark plan. For States that choose § 156.111(a)(1) or (a)(2) where the State is developing its benchmark plan based on another State's EHB-benchmark plan, the State could develop this document utilizing information from the EHB summary chart that is currently publicly available.[73]

We proposed that HHS would post the State's EHB summary document and the State's EHB-benchmark plan document on the Center for Consumer Information and Insurance Oversight (CCIIO) website. We also considered posting the State's EHB-benchmark plan confirmations proposed at § 156.111(e)(1).

We proposed that in order for a State's selection of a new EHB-benchmark plan from the proposed options to be accepted, the State's new EHB-benchmark plan must comply with the associated EHB regulatory and statutory requirements, including those under this final rule. If a State's EHB-benchmark plan selection does not meet these regulatory and statutory requirements, the State's current EHB-benchmark plan would continue to apply. We solicited comments on the proposed processes and deadlines for the 2019 and 2020 plan years.[74] We also solicited comments on the proposed data collection and associated documents and whether other specifications for these documents are needed. We are finalizing the provisions at § 156.111(e) with an amendment to § 156.111(e)(2) to reflect the changes to § 156.111(b)(2)(i) and (ii) described above. We are finalizing that the policy will begin applying for the 2020 plan year.

Comment: Commenters generally supported transparency in EHB-benchmark plan documents and making these documents publicly available. Some commenters noted concerns about the completeness and accuracy of current EHB-benchmark plan documents and the inconsistent level of detail among EHB summary charts, encouraging accuracy in plan information to limit confusion.

Response: Section 156.111(e) is designed to ensure that the State's EHB-benchmark plan meets the requirements at § 156.111(b), (c), and (d) and to ensure that the State's EHB-benchmark plan has a clearly defined set of covered benefits. In an effort to support transparency, we will post all documents[75] that a State submits pertaining to its EHB-benchmark plan selection on CCIIO's website with the exception of the drug list. These documents will include the State's confirmations (§ 156.111(e)(1)), any actuarial certification and associated actuarial report (§ 156.111(e)(2)), the plan documents (§ 156.111(e)(3)), and the documents necessary to operationalize the State's EHB-benchmark plan (§ 156.111(e)(4)). The State's EHB-benchmark plan drug list will be posted in the category and class count format in the EHB summary chart as the current drug counts are currently posted.[76]

Because EHB-benchmark plan benefits are based on plans that were sold in 2014, some of the benchmark plan documents may not comply with current Federal requirements. For this reason, the State confirmations require the State to confirm that its EHB-benchmark plan meets the requirements to be an EHB-benchmark plan. Since States are typically the primary enforcer of EHB policy, States may take varying approaches to the level of details included in the EHB Summary Chart, as we believe the manner in which the State displays the EHB-benchmark plan in the EHB Summary Chart may be reflective of the State's EHB enforcement strategies.

Furthermore, we also recognize that the States' 2017 EHB-benchmark plans may need conforming edits to comply with other laws and regulations, and to account for any benefits considered EHB under § 155.170. For these reasons, we clarified in the proposed rule that benefits and limits described in the available benchmark plan documents on our website may not be fully applicable due to other laws and regulations. For instance, under section 2711 of the PHS Act, as added by the PPACA, issuers may not impose lifetime or annual dollar limits on EHBs. When lifetime or annual dollar limits are specified in available EHB-benchmark plan documents, States would have removed the dollar limits or converted them to non-dollar limits when interpreting and applying EHB policy. HHS recognizes most States as the primary enforcers of EHB policy. Thus, when a State would use an EHB-benchmark plan that originated in another State under any proposals under § 156.111, we would generally defer to the selecting State's implementation of the benefits and limits consistent with otherwise applicable law, even when such interpretation differs from the originating State's interpretation. Where possible, States should provide clarity on benefits and limits in the documents collected under § 156.111(e) or note differences in the States' EHB summary chart.

Lastly, we are codifying in regulation text at § 156.111(d)(1) a proposed standard that we discussed in the preamble of the proposed rule, under which the State's new EHB-benchmark plan must comply with the regulatory

[73] All States' current benchmark plan documents are posted on CCIIO's website at *https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html.*

[74] For the 2019 plan year, HHS would post States' EHB-benchmark plan documents after the proposed State submission deadline, which would likely be in April 2018.

[75] CMS's PRA website is available at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

[76] *https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html.*

and statutory requirements, including those under this final rule, in order for HHS to accept a State's selection of a new EHB-benchmark plan from the options under § 156.111(a). If a State's EHB-benchmark plan selection does not meet these regulatory and statutory requirements, the State's current EHB-benchmark plan would continue to apply.

Comment: Some commenters on the *Draft Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection to Benefits of a Typical Employer Plan As Proposed under the HHS Notice of Benefit and Payment Parameters for 2019 (CMS–9930–F)* did not support parts of the proposed methodological approach. Comments generally did not support the use of small group index rates or wanted an upper-bound limit of 98 percent to 102 percent for the category comparison, with some commenters, noting the difficulty in conducting this type of calculation or recommending additional input or more detail. Others wanted to require actuarial data from the States to justify adoption of a benchmark plan that varies significantly from their current benchmarks in any category. Comments on the actuarial certification and associated actuarial report requirements varied on which EHB-benchmark selection options it should apply to.

Response: To account for the application of the typical employer plan definition at § 156.111(b)(2)(i) and the generosity standard at § 156.111(b)(2)(ii) to all selection options, we are finalizing § 156.111(e)(2) with certain changes. Specifically, we are finalizing the requirement that States provide an actuarial certification and an associated report from an actuary from the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies, that affirms: (1) That the State's EHB-benchmark plan provides a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan as defined at § 156.111(b)(2)(i); and (2) the State's EHB-benchmark plan does not exceed the generosity of the most generous among the set of comparison plans at § 156.111(b)(2)(ii)(A) and (B). States will be required to submit an actuarial certification and an associated report under § 156.111(e)(2) to affirm that both of the standards at § 156.111(b)(2)(i) and § 156.111(b)(2)(ii) are met, regardless of which selection option under § 156.111(a) they use.

The purpose of the policy being finalized at § 156.111 is to strike a balance between providing flexibility to allow States' additional options to select their EHB-benchmark plans and ensuring that States' EHB-benchmark plans meet the associated statutory requirements. To that end, the actuarial certification and associated actuarial report are intended to ensure that the scope of EHB is equal in scope to the benefits provided under a typical employer plan, and to provide the information to support the certification from the Chief Actuary of CMS for the Secretary to submit along with a report to Congress, consistent with section 1302(b)(2)(B) of the PPACA. Section 1302(b)(2)(B) of the PPACA requires that the Chief Actuary of CMS certify that the scope of EHB as defined by the Secretary is equal to the scope of benefits provided under a typical employer plan. Through this rule, the Secretary is determining that the actuarial certification and associated actuarial report at § 156.111(e)(2) ensures any EHB-benchmark plan selection is meeting the requirements at section 1302(b)(2)(A) of PPACA; therefore, we are finalizing these requirements.

This includes the requirement that the actuarial certification and associated actuarial report be prepared in accordance with generally accepted actuarial principles and methodologies. This includes all applicable ASOPs. For example, ASOP 41 contains disclosure requirements, including those that apply to the disclosure of information on the methods and assumptions being used and ASOP 50 contains information on determining MV and AV. In accordance with ASOP 41, we would expect that the actuarial report is based on a data analysis that is reflective of an appropriate population.

State actuaries may need flexibility in developing the actuarial certification and report depending on the type of changes that the State is interested in making to its EHB-benchmark plan and depending on the typical employer plan that the State is using for the certification and report. For these reasons, we are finalizing an example methodology with several changes.[77] First, to provide clarification for actuaries, we expanded the methodology to address the determination of the plan generosity under § 156.111(b)(2)(ii) in parallel to the determination of the typical employer plan, and further explained how an actuary could use a typical employer plan or a comparison plan for this certification and associated report.

Second, we are finalizing the definition of a typical employer plan to establish the minimum level of benefits for the State's EHB-benchmark plan and the generosity standard to establish the maximum level of benefits for a State's EHB-benchmark plan selection. By tying the maximum level of benefits, in part, to certain previous States' EHB-benchmark plan options, the new State EHB-benchmark plan selections are tied to generosity of the current EHB-benchmark plans in the States, which is not what a 102 percent upper bound limit would provide. For these reasons, we believe that creating an additional upper-bound limit under the typical employer plan in the example methodology is not necessary, would be duplicative, and would be difficult to implement with the generosity standard at § 156.111(b)(2)(ii).

Lastly, to support the use of more appropriate data for the actuarial certification and associated actuarial report, we removed the use of small group index rates from the calculation of the expected value. Instead, we provide other examples of acceptable data that an actuary may use, including data acquired from issuers in the State for a recent plan year, and weighted the services and benefits provided in each EHB category. We believe that the changes to the methodology will help inform actuaries on how to approach the actuarial certification and associated report at § 156.111(e)(2).

Comment: Commenters generally opposed implementing the new EHB-benchmark plan options for the 2019 benefit year. Some of these commenters were concerned about operational and administrative feasibility and burden to implement an EHB change for 2019, as well as the lack of adequate time to design products and meet 2019 rate and form filing deadlines. Other commenters were concerned about the ability for States and issuers to evaluate options, or the impact of the policy leading to market instability, increased costs, or consumer confusion. Some commenters noted that the goal of market stability was more important than the goal of providing States with added flexibility. Another commenter was concerned about the potential for data errors due to short timeframes.

Commenters generally supported making EHB-benchmark plan changes for the 2020 plan year at the earliest, with some noting that the 2020 timelines aligns with previous

[77] *Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with 45 CFR 156.111(b)(2)(i) and (ii)* is available at *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.html.*

benchmark plan timelines. Certain commenters wanted additional analysis or information before implementing any change. Other commenters wanted to ensure that States provide outreach to consumers on the EHB-benchmark plan changes. A commenter wanted to understand how guaranteed renewability might affect changes to plans being made to reflect changes from a new State EHB-benchmark plan selection.

Response: We acknowledge the operational and administrative difficulties for States, issuers and consumers with implementing a changing benefit design under the timeframes for the 2019 benefit year, and believe that a 2020 implementation date would provide these stakeholders with additional time to ensure a smooth implementation of any benefit design changes. For these reasons, we will make § 156.111 effective for the 2020 plan year. We are also finalizing the deadline for State submission of its EHB-benchmark plan as July 2, 2018, for the 2020 plan year.[78] This deadline aligns with the timing of HHS's previous updates to the benchmark plans.

As for guaranteed renewability, under some circumstances, issuers may be permitted to change their products to reflect new requirements for providing EHB as uniform modifications of their products. Otherwise, if the changes to products are deemed to result in the removal of products from the market, issuers would be required to meet the product discontinuance requirements under § 147.106, which generally require at least 90 days advanced notice to the enrollees of the discontinuance.

c. Provision of EHB (§ 156.115)

Currently, to provide EHB, plans are required to provide benefits that are substantially equal to the EHB-benchmark plan. However, an issuer of a plan offering EHB may substitute benefits *within* categories, if allowed by the State, provided that the benefits are actuarially equivalent to the benefit that is being replaced. Substitutions of prescription drug benefits are not permitted.[79] In the EHB Rule, we finalized a policy at § 156.115(b)(1) under which substitution may not occur between different benefit categories.

In an effort to promote greater flexibility, consumer choice, and plan innovation through coverage and plan design options, we proposed modifying paragraph (b)(1)(ii) to allow States to permit issuers to substitute benefits within the same EHB category *and* between EHB categories, as long as the substituted benefit is actuarially equivalent to the benefit being replaced and is not a prescription drug benefit. The plan with substitutions would still be required to provide benefits that are substantially equal to the EHB-benchmark plan, to provide an appropriate balance among the EHB categories such that benefits are not unduly weighted towards any category, and to provide benefits for diverse segments of the population. It is generally the State's responsibility to assess that plans required to provide EHB adhere to these requirements.

We noted that nothing in this proposal would prohibit plans required to provide EHB from imposing non-dollar limits, unless otherwise prohibited by Federal law.[80] In addition, we noted that we would continue to defer to States, which have the option to set criteria for benefit substitution, to enforce a stricter standard on benefit substitution, or to prohibit it altogether consistent with paragraph (b) of this section. We sought comment on examples of substitution that issuers would be interested in pursuing.

We are finalizing the proposal with amendments to clarify when issuers may substitute benefits and States' roles in permitting or prohibiting substitution. Specifically, we are finalizing the change to allow issuers to substitute benefits between EHB categories, beginning with plan year 2020, if the State in which the plan will be offered permits such substitution and notifies HHS of its decision to allow substitution between categories. We also add a clarification at § 156.115(b)(3)(i) that plans with substitutions are not relieved of their requirements under § 156.115(a), including the requirement to cover preventive health services, as required under 45 CFR part 147.

We are finalizing 2020 as the first plan year in which issuers, with the permission of the State, may substitute benefits between categories to align with the first year for which States may update their EHB-benchmark plans under § 156.111.

We believe States are best positioned to weigh the benefits of innovative plan design with any effects on State risk pools, and therefore, will only permit substitution between EHB categories in States that have notified HHS that substitution between EHB categories is permitted by the State. Further, because States are generally the primary enforcers of EHB requirements, including the prohibition on discrimination at § 156.125, we believe States can best assure that plan designs meet the needs of their State residents. We anticipate that States will notify HHS of their decision, if any, to allow substitution between EHB categories through the same means States use to notify HHS of an updated EHB-benchmark plan selection under § 156.111. If a State wishes to permit between-category substitution, it will notify HHS, and that notification will be in effect unless and until the State notifies HHS otherwise. States that permit between-category substitution should work with their issuers to ensure they are aware of this option. We plan to post on CCIIO's website a list of States that allow substitution between EHB categories.

Comment: The majority of commenters to this proposal expressed concerns about this proposed policy, and many commenters to this proposal raised concerns about this policy's potential impact on the risk pool. Specifically, commenters were concerned that the proposal would permit issuers to design products that are intended to be unattractive to higher-cost populations to discourage enrollment from these populations. Some of these commenters were concerned about resulting adverse selection, and were concerned that finalizing the policy could ultimately interfere with the stability of the individual and small group market risk pools. Several commenters were concerned that the requirement that substituted benefits be actuarially equivalent does not address this concern, because actuarial equivalence is based on a standard population and cannot take into account the potential effects of adverse selection. Commenters were concerned that this type of ''gaming'' to deter enrollment from members of certain groups could undermine State risk adjustment programs. Additionally, many commenters requested that if we chose to finalize this proposal, we publish additional guidance clarifying how issuers could utilize substitution between EHB categories without violating antidiscrimination

[78] We proposed July 1, 2018, but recognize that July 1, 2018 is a Sunday, so we are finalizing the 2020 deadline as July 2, 2018.

[79] See § 156.115(b)(1)(iii), as established in the EHB Rule.

[80] See Frequently Asked Questions on Essential Health Benefits Bulletin (February 17, 2012), Q9, available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf* and the EHB rule. As finalized in the EHB Rule, issuers of QHPs were permitted to make actuarially equivalent substitutions within statutory categories under § 156.115(b)(1)(ii). Therefore, and as further explained in the EHB FAQ, plans are permitted to impose non-dollar limits, consistent with other guidance, that are at least actuarially equivalent to the annual dollar limits.

requirements. Some commenters stated that they could not conceive of a situation in which cross-category substitution would be useful, and notwithstanding our request for such examples, we did not receive any.[81]

Response: We seek to promote issuer flexibility and consumer choice with this proposal, but recognize that there are potential trade-offs with regard to the risk pool and risk adjustment programs. We believe that States are more attuned to the needs of their issuers and consumers than HHS and can better assess the proper balance between flexibility in plan benefits and risk pool stability. Because issuers are required under the rule to provide benefits that are substantially equal to the EHB-benchmark plan, provide an appropriate balance among the EHB categories such that benefits are not unduly weighted towards any category, and provide benefits for diverse segments of the population, we expect that effects on the risk pool will be limited and can be appropriately managed through State regulation. Because States are generally the primary enforcers of the prohibition on discrimination in the provision of EHB, we defer to States to provide guidance to issuers on how to utilize substitution while meeting anti-discrimination requirements.

Comment: While commenters generally supported efforts to provide States and issuers with additional flexibility, a majority of commenters expressed strong concerns that this specific policy would put undue burden on multiple stakeholders due to increased plan design complexity. For example, many commenters wrote that regulators in States that choose to permit substitution between EHB benefit categories would face additional challenges due to the difficulty of determining whether plans that substituted benefits between EHB offered an adequate distribution of benefits across all EHB categories. One commenter added that evaluating plans that incorporated substitution between EHB categories would be more difficult for States than evaluating plans with substitution within EHB categories, because when comparing the allowed cost associated with particular types of services and limits on those services with other services in the same EHB category, the same dollar amount represents the same proportion of all services in that EHB category. However, this equivalence of dollar amounts and proportionality does not apply when comparing between different categories, making a comparison more difficult. Relatedly, another commenter noted that the lack of uniformity among plans this policy could produce could increase administrative burden on issuers, as well as States, by making it more difficult for issuers to conform plans to filing templates related to QHP certification.

Due to concerns including additional burden on State regulators, commenters also requested that if we were to finalize this proposal, States be permitted to bar substitution between EHB categories.

Almost all commenters asked that we consider the increased burden that consumers would face when comparing plans due to plan complexity related to a possible lack of uniformity across EHB benefit categories and across available plans. In particular, commenters noted that it would become more difficult for consumers in States that chose to permit this option to make meaningful comparisons between plans due to the difficulty in determining whether benefits had been substituted between EHB categories and, if so, whether the resulting coverage package adequately met their needs. One commenter added that these difficulties could also undermine the value of the market signals that consumers' choices currently generate to issuers and other key stakeholders.

Finally, in addition to concerns about consumer burden due to increased plan complexity, many commenters also objected to this proposal due to the possibility that it could undermine coverage for services that are crucial for vulnerable consumers and prevent coverage of chronic conditions.

Response: We agree that permitting substitution between EHB categories could make it more difficult for State regulators to review plans. However, we believe States should have the flexibility to determine whether allowing such a policy will in fact create challenges for State regulators, and if so, whether those challenges are offset by the benefits of allowing more innovation in plan design in the form of between-category substitution. Under the policy we are finalizing, States that determine that allowing substitution between EHB categories would pose excessive burden on regulators have the authority to withhold permission and avoid such burden.

In response to comments, we are finalizing that substitution between categories would only be permitted if the State in which the plan will be offered has notified HHS that substitution between EHB categories is permitted in the State. We recognize that State legislative cycles may make it challenging for States to adopt legislative requirements allowing or prohibiting substitution between categories in time for plan year 2020. By finalizing this notification approach, we seek to make it easier for States to immediately exercise the flexibility provided in this rule.

We appreciate the comment about increased burden on issuers. Because issuers are already familiar with substituting benefits within benefit categories, we do not believe that broadening the policy to allow benefit substitution between benefit categories will create additional burden for issuers. However, if it does, issuers have the discretion to avoid additional burden by choosing not to substitute benefits between EHB categories, even if allowed by their State. If a State chooses, we believe issuers should be permitted to decide whether the additional flexibility in plan design provided by substitution between categories is worth any additional required effort. We also encourage States to consider the impact on issuers as they weigh whether to allow substitution between categories.

We recognize that consumers may face some additional burden in comparing plans when States allow between-benefit substitution and one or more issuers in the State utilize such substitution. However, we believe permitting substitution between categories could offer significant benefit to consumers in the form of more choices, particularly those actively engaged in shopping for health plans. Some consumers are likely to find plans that better meet their needs under this change, because issuers are likely to make substitutions that fulfill consumer demands. Further, we believe States are best positioned to weigh the benefits of innovative plan design with the potential for increased burden for consumers in their individual and small group markets.

We believe that this change will not undermine coverage for vulnerable consumers or prevent coverage of chronic conditions, because issuers will still be required to offer benefits substantially equal to the EHB-benchmark plan, cover each EHB category without undue weight toward any, provide benefits for diverse segments of the population, and refrain from discrimination based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

[81] One commenter submitted what they described as an example of how an issuer could use this policy to promote the use of high-value services, but their example was a case of adjustments to actuarial value, as opposed to an example of substitution between EHB categories.

d. Premium Adjustment Percentage (§ 156.130)

Section 1302(c)(4) of the PPACA directs the Secretary of HHS to determine an annual premium adjustment percentage, which is used to set the rate of increase for three parameters detailed in the PPACA: The maximum annual limitation on cost sharing (defined at § 156.130(a)); The required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code;[82] and the assessable payment amounts under section 4980H(a) and (b) of the Code. Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and that this percentage will be published in the annual HHS notice of benefit and payment parameters.

Under the methodology established in the 2015 Payment Notice and amended in the 2015 Market Standards Rule for estimating average per capita premium for purposes of calculating the premium adjustment percentage, the premium adjustment percentage is calculated based on the estimates and projections of average per enrollee employer-sponsored insurance premiums from the NHEA, which are calculated by the CMS Office of the Actuary. Accordingly, using the employer-sponsored insurance data, the premium adjustment percentage for 2019 is the percentage (if any) by which the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2018 ($6,396) exceeds the most recent NHEA estimate of per enrollee employer-sponsored insurance premiums for 2013 ($5,110).[83] Using this formula, the premium adjustment percentage for 2019 is 1.2516634051 or approximately 25 percent. We are finalizing this index as proposed. Based on the proposed 2019 premium adjustment percentage, we proposed the following cost-sharing parameters for calendar year 2019.

Maximum Annual Limitation on Cost Sharing for Calendar Year 2019

Under § 156.130(a)(2), for the 2019 calendar year, cost sharing for self-only coverage may not exceed the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2019, and for other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Under § 156.130(d), these amounts must be rounded down to the next lowest multiple of $50. Using the premium adjustment percentage of 1.2516634051 for 2019 as proposed above, and the 2014 maximum annual limitation on cost sharing of $6,350 for self-only coverage, which was published by the IRS on May 2, 2013,[84] we proposed that the 2019 maximum annual limitation on cost sharing would be $7,900 for self-only coverage and $15,800 for other than self-only coverage. This represents an approximately 7 percent increase above the 2018 parameters of $7,350 for self-only coverage and $14,700 for other than self-only coverage.

Comment: Several commenters supported the 7 percent increase in the maximum limitation on cost sharing, saying it permits flexible plan design. Many other commenters objected to the 2019 maximum limitation on cost sharing noting it is the highest increase since 2014, saying the HHS methodology no longer works when paired with plan designs that offer less generous EHBs and asked HHS to revisit factors including the premium adjustment percentage used in the methodology.

Commenters noted that while many people with high health needs benefit from a maximum limitation on cost sharing, the percentage increase in 2019 is more than twice the rate of medical inflation and wage growth and far higher than general inflation. Two commenters asked HHS to spread the maximum limitation over the benefit year to reduce the financial burden on chronically ill enrollees whose medical conditions require them to meet the limitation during the first month or quarter of the year.

Response: The annual maximum limitation on cost sharing reflects changes in the underlying economic data, as stated above. We are sympathetic to the hardship faced by those whose health needs require them to meet their maximum limitation on cost sharing early in the year, but the indexing of this parameter is required by statute, and a payment plan for the maximum annual limitation is inconsistent with industry practice. We are finalizing the 2019 maximum limitation on cost sharing as proposed.

e. Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

Sections 1402(a) through (c) of the PPACA direct issuers to reduce cost sharing for EHBs for eligible individuals enrolled in a silver level QHP. In the 2014 Payment Notice, we established standards related to the provision of these cost-sharing reductions. Specifically, in part 156, subpart E, we specified that QHP issuers must provide cost-sharing reductions by developing plan variations, which are separate cost-sharing structures for each eligibility category. At § 156.420(a), we detailed the structure of these plan variations and specified that QHP issuers must ensure that each silver plan variation has an annual limitation on cost sharing no greater than the applicable reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters. Although the amount of the reduction in the maximum annual limitation on cost sharing is specified in section 1402(c)(1)(A) of the PPACA, section 1402(c)(1)(B)(ii) of the PPACA states that the Secretary may adjust the cost-sharing limits to ensure that the resulting limits do not cause the AVs of the health plans to exceed the levels specified in section 1402(c)(1)(B)(i) of the PPACA (that is, 73 percent, 87 percent, or 94 percent, depending on the income of the enrollee). Accordingly, we proposed to continue to use a method we established in the 2014 Payment Notice for determining the appropriate reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations. As we discussed above, the 2019 maximum annual limitation on cost sharing is $7,900 for self-only coverage and $15,800 for other than self-only coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. Below, we describe our analysis for the 2019 benefit year and our proposed results.

Consistent with our analysis in the 2014 through 2018 Payment Notices, we developed three test silver level QHPs, and analyzed the impact on AV of the reductions described in the PPACA to

[82] As noted above, although the individual shared responsibility payment in section 5000A is reduced to $0, effective for months beginning after December 31, 2018, individuals may still have a need to seek certain exemptions under section 5000A of the Code to obtain catastrophic coverage after 2018.

[83] We note that the 2013 premium used for this calculation has been updated to reflect the latest NHEA data. See ''NHE Projections 2016–2025—Tables'' available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html* in Tables 1 and 17. A detailed description of the NHE projection methodology is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf.*

[84] *See http://www.irs.gov/pub/irs-drop/rp-13-25.pdf.*

the estimated 2019 maximum annual limitation on cost sharing for self-only coverage ($7,900). The test plan designs are based on data collected for 2017 plan year QHP certification to ensure that they represent a range of plan designs that we expect issuers to offer at the silver level of coverage through the Exchanges. For 2019, the test silver level QHPs included a PPO with typical cost-sharing structure ($7,900 annual limitation on cost sharing, $2,350 deductible, and 20 percent in-network coinsurance rate), a PPO with a lower annual limitation on cost sharing ($5,250 annual limitation on cost sharing, $3,050 deductible, and 20 percent in-network coinsurance rate), and an HMO ($7,900 annual limitation on cost sharing, $3,375 deductible, 20 percent in-network coinsurance rate, and the following services with copayments that are not subject to the deductible or coinsurance: $500 inpatient stay per day, $500 emergency department visit, $25 primary care office visit, and $55 specialist office visit). All three test QHPs meet the AV requirements for silver level health plans.

We then entered these test plans into the proposed 2019 AV Calculator and observed how the reductions in the maximum annual limitation on cost sharing specified in the PPACA affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 100 and 150 percent FPL (⅔ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of the FPL (⅔ reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV levels (94 and 87 percent, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 200 and 250 percent of FPL (½ reduction), would cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. As a result, we proposed that the maximum annual limitation on cost sharing for enrollees in the 2017 benefit year with a household income between 200 and 250 percent of FPL be reduced by approximately ⅕, rather than ½. We further proposed that the maximum annual limitation on cost sharing for enrollees with a household income between 100 and 200 percent of the FPL be reduced by approximately ⅔, as specified in the statute, and as shown in Table 10. These proposed reductions in the maximum annual limitation on cost sharing should adequately account for unique plan designs that may not be captured by our three model QHPs. We also note that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute would not reduce the benefit afforded to enrollees in aggregate because QHP issuers are required to further reduce their annual limitation on cost sharing, or reduce other types of cost sharing, if the required reduction does not cause the AV of the QHP to meet the specified level. We are finalizing these reductions as proposed.

In prior years, we have found that for individuals with household incomes of 250 to 400 percent of the FPL, without any change in other forms of cost sharing, any reduction in the maximum annual limitation on cost sharing will cause an increase in AV that exceeds the maximum 70 percent level set in the statute. In the Market Stabilization Rule, we analyzed the effect of reducing the maximum annual limitation on cost sharing based on how we calculated the 2018 reduced maximum annual limitation on cost sharing. We stated that we were not certain what the AV spread of plan designs will be under the finalized policy, whether issuers will in fact reduce the AVs of their base silver plans to the lower end of the *de minimis* range, and whether issuers will retain plan designs above the 70 percent AV range and that we would monitor 2018 standard silver plan designs. As a result, we did not propose to reduce the maximum annual limitation on cost sharing for individuals with household incomes between 250 and 400 percent FPL.[85]

We note that for 2019, as described in § 156.135(d), States are permitted to submit for approval by HHS State-specific datasets for use as the standard population to calculate AV.[86] No State submitted a dataset by the September 1, 2017 deadline.

TABLE 10—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2019

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2019	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2019
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (that is, 100–150 percent of FPL)	$2,600	$5,200
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (that is, 150–200 percent of FPL)	2,600	5,200
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (that is, 200–250 percent of FPL)	6,300	12,600

Comment: Several commenters objected to reducing the maximum annual limitation on cost sharing by only one-fifth for enrollees with 200–250 percent FPL, calling the resulting reduced maximum annual limitation on cost sharing about 28 percent of income in this category and too high for most consumers. Commenters asked HHS to revise its test plan, with one commenter saying it does not reflect shifts in plan network type and structure and, as a result, hurts enrollees in this income level.

Response: When developing our test plan, we generally try to match features of actual 2018 plans submitted for certification. We understand State-by-State plans may differ from the HHS test plans and we will continue to apply statutory reductions in maximum annual limitation on cost sharing to plans that most accurately represent those submitted for certification.

[85] 2014 Payment Notice, 78 FR at 15481; Market Stabilization Rule. 82 FR at 18370–18371.

[86] The annual deadline for submitting State specific data for the AV Calculator was announced August 15, 2014. See *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/final-state-avc-guidance.pdf.*

Comment: One commenter cautioned HHS against introducing a new plan variation for enrollees with incomes between 250–400 percent FPL in the absence of Federal payments to issuers for cost-sharing reductions, stating that additional requirements to provide reduced cost sharing would cause issuers to increase premium for all enrollees, and disproportionately hurt those not eligible for any or all subsidies.

Response: We share the commenter's concern that additional reductions for some enrollees could result in higher charges for others without other changes. We will continue to monitor plan AV and benefit design for impact on premiums and out-of-pocket costs.

f. Application to Stand-Alone Dental Plans Inside the Exchange (§ 156.150)

Section 1302(d)(2) of the PPACA directs the Secretary to issue regulations on the calculation of AV and its application to the levels of coverage. In the 2013 EHB Rule, HHS finalized the requirements for the calculation of AV for stand-alone dental plans. Specifically, § 156.150 directs SADPs to cover the pediatric dental EHB at one of two AV levels, within an allowable de minimis variation of +/− 2 percentage points.

We proposed to remove the requirement under § 156.150(b) for SADP issuers to meet the low (70 percent +/− 2 percentage points) or high (85 percent +/− 2 percentage points) AV level. We are finalizing the elimination of the requirement that SADP issuers offer EHBs at the low or high levels of coverage. The PPACA does not specifically require SADP issuers to offer coverage at the high or low levels of AV. Removing the AV level requirement will give SADP issuers the opportunity to offer more flexible plan designs to consumers. In previous comments, SADP issuers had noted that it is difficult to meet the low AV requirement and offer preventive care without cost sharing, to which consumers are accustomed in the large group market. Issuers could offer SADPs at varying premiums and levels of coverage, so long as they continue to offer the pediatric dental EHB and meet the annual limitations on cost sharing. We believe that this will allow consumers to select from a greater variety of plans and find one that is more likely to meet their specific needs.

We are not finalizing the elimination of the requirement that SADP issuers certify their plans' level of coverage of EHB, as proposed. We will no longer require certification of the level of coverage since SADPs will no longer be required to be offered at certain levels of coverage. However, HHS will continue to require certification by a member of the American Academy of Actuaries of the AV of the SADPs' coverage of EHB. HHS will consider ways to use the certified AV to provide consumers with additional information to assist in plan selection.

Comment: Several commenters opposed the proposal. They expressed concern that the removal of AV requirements for EHB would allow SADP issuers to offer plans with little value, and that consumers would have difficulty comparing SADPs. Several commenters requested that HHS establish a minimum AV of 70 percent for EHB covered by SADPs, and that the level of coverage of EHB of an SADP be displayed to consumers when they choose plans.

Several commenters supported the proposal. They expected the proposal to result in greater plan choice for consumers. Some also expected SADPs to have greater ability to maintain similar cost sharing from year to year, since SADP issuers would not be required to alter their plans to meet a particular level of coverage. One commenter observed that AV for pediatric EHB is a poor indicator of plan value for SADPs, since most SADP enrollees are adults. Some commenters requested that HHS implement consumer support tools to aid consumers in choosing among SADPs.

Response: In order to facilitate the implementation of consumer support tools related to SADPs in the future, we are not finalizing the elimination of the requirement that SADPs' AV for EHB be certified by a member of the American Academy of Actuaries. Further, we are codifying an operational requirement that such certification be reported to the Exchange, which issuers of SADPs have already been fulfilling, as part of the QHP certification process.

We believe consumers benefit when they have a range of plan choices, including some plans with lower premiums and a lower AV. All SADPs will continue to be required to cover the pediatric dental EHB and to limit annual cost sharing on EHB. We expect many SADPs with AVs at and above 70 percent will remain available to consumers, even without a minimum AV standard, because SADPs often provide preventive services without cost sharing. While we acknowledge that removing AV standards will make plan comparison more difficult for some consumers, we note that standardized levels of coverage of pediatric dental EHB are not a useful plan comparison tool for the large share of SADP enrollees who are adults. HHS will consider ways to provide consumers with additional information to assist in comparison and selection of SADPs.

Comment: Some commenters questioned whether an SADP with a different AV from one year to the next would be considered the same plan for the purposes of guaranteed renewability or plan crosswalk.

Response: We note that guaranteed renewability requirements at 45 CFR 147.106 generally do not apply to SADPs because they are excepted benefit plans. HHS plans to develop a plan crosswalk hierarchy for Exchanges that use the Federal eligibility and enrollment platform that does not rely on SADPs being offered at either a high or low level of coverage.

3. Qualified Health Plan Minimum Certification Standards

a. Qualified Health Plan Certification (Subpart C)

HHS is committed to recognizing States' role as the primary regulator of their insurance markets, and has made a number of recent changes in the QHP certification process to promote this role, and to limit duplicative oversight over issuers. Previously, in the Guidance to States on Review of Qualified Health Plan Certification Standards in Federally-facilitated Marketplaces for Plan Years 2018 and Later,[87] released on April 13, 2017, we outlined areas where, starting in plan year 2018, HHS began relying on State reviews of QHP certification standards for States with FFEs, including States with FFEs that perform plan management functions in partnership with HHS. We made these changes to streamline the QHP certification process and avoid duplicative Federal and State efforts. In that guidance, we provided that in FFE States that do not perform plan management functions, HHS will continue to review QHP data, but will rely on State review for licensure and good standing standards required at § 156.200(b)(4), and for network adequacy standards required at § 156.230. For FFEs in States performing plan management functions, HHS will continue to rely on State plan data review for QHP certification standards, including for service area and prescription drug formulary outliers and non-discrimination in cost sharing. We stated that we will continue to review plan data relating to Federal funds or plan display on *HealthCare.gov*, such as cost-sharing reductions structures, data

[87] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QHP-Certifcation-Reviews-Guidance-41317.pdf.*

integrity, and plan crosswalks to implement annual re-enrollment at § 155.335(j). In the proposed rule, we reaffirmed this approach, and did not propose changes to this guidance.

To further streamline QHP certification by avoiding duplicative reviews, we also previously announced in the QHP Rate Outlier Analysis for Plan Year 2018 and Beyond [88] that we would rely on States to identify rate outliers for purposes of QHP certification,[89] except for those States that do not have an Effective Rate Review Program. These changes were intended to allow States and issuers greater flexibility in facilitating the certification of plans best suited to their markets, while avoiding duplicative State and Federal activities. We did not propose any changes to the approach described in this guidance.

In the Market Stabilization final rule, HHS also finalized several standards to affirm the traditional role of States in overseeing their health insurance markets while reducing the regulatory burden of participating in Exchanges for issuers for the 2018 plan year.

In the proposed rule, we continued these efforts to enhance States' role in the QHP certification process. We proposed to continue to enhance the State flexibilities in QHP certification that began for plan year 2018 by identifying additional areas where States are already performing reviews that are duplicative of the Federal QHP certification process and incorporating these reviews into the QHP certification process. In addition to empowering States, we believed these proposals would reduce issuer burden.

We proposed to extend for the 2019 benefit year and beyond policies related to QHP certification standards for network adequacy (§ 156.230) and essential community providers (§ 156.235) that we had finalized in the Market Stabilization final rule for only plan year 2018. Specifically, with respect to network adequacy, we proposed to rely on the States' reviews in States in which an FFE is operating, provided the State has a sufficient network adequacy review process. For the 2019 benefit year and beyond, we proposed to defer to the States' reviews in States with the authority to enforce standards that are at least equal to the ''reasonable access standard'' defined in § 156.230 and means to assess issuer network adequacy. In States that do not have the authority and means to conduct sufficient network adequacy reviews, we proposed for the 2019 benefit year and beyond to rely on an issuer's accreditation (commercial, Medicaid, or Exchange) from an HHS-recognized accrediting entity, which we proposed would include the three accrediting entities HHS has previously recognized for the accreditation of QHPs: The National Committee for Quality Assurance, URAC, and Accreditation Association for Ambulatory Health Care.[90] Unaccredited issuers would be required to submit an access plan as part of the QHP application. To show that the QHP's network meets the requirement in § 156.230(a)(2), the access plan would need to demonstrate that an issuer has standards and procedures in place to maintain an adequate network consistent with the National Association of Insurance Commissioners' Health Benefit Plan Network Access and Adequacy Model Act (the Model Act is available at *http://www.naic.org/store/free/MDL-74.pdf*). We proposed to further coordinate with States to monitor network adequacy, for example, through complaint tracking.

With respect to QHP certification review for the essential community provider (ECP) standard, we proposed for the 2019 benefit year and beyond that we would continue to allow issuers to use the ECP write-in process to identify ECPs that are not on the HHS list of available ECPs and would maintain the 20 percent ECP standard. We believe this standard will substantially reduce the regulatory burden on issuers while preserving adequate access to care provided by ECPs. As in previous years, if an issuer's application does not satisfy the ECP standard, the issuer would be required to include as part of its application for QHP certification a satisfactory narrative justification describing how the issuer's provider networks, as presently constituted, provide an adequate level of service for low-income and medically underserved individuals and how the issuer plans to increase ECP participation in the issuer's provider networks in future years. At a minimum, such narrative justification would include the number of contracts offered to ECPs for the applicable plan year; the number of additional contracts an issuer expects to offer and the timeframe of those planned negotiations; the names of the specific ECPs to which the issuer has offered contracts that are still pending; and contingency plans for how the issuer's provider network, as currently designed, will provide adequate care to enrollees who might otherwise be cared for by relevant ECP types that are missing from the issuer's provider network.

We are finalizing as proposed the policies for network adequacy (§ 156.230) and ECPs (§ 156.235).

Comment: Many commenters supported the network adequacy proposal, favoring the elimination of duplicative reviews, while others opposed the proposal, stating that States' and accrediting entities' review processes do not do enough to ensure enrollees have adequate access to necessary care. We also received many comments that strongly opposed the continuation of the 20 percent ECP standard and urged that HHS return to the 30 percent ECP standard, expressing concerns that the lower threshold requirement will result in access barriers to care for low-income consumers.

Response: We are finalizing as proposed our policies for network adequacy and ECP, as we believe they will continue to help stabilize the markets by reducing regulatory burden on issuers, while also preserving adequate access to care, and streamlining the QHP certification process. We have relied on State and accrediting entities for this review in the past, and believe they provide appropriate review because both typically have requirements in place that specifically address access to adequate networks. Many States already address issuer network adequacy in State-specific regulation. The National Committee for Quality Assurance requires accredited plans to create standards for the number and geographic distribution of providers and establish standards regarding the ability of consumers to access care. Similarly, URAC requires that plans have proper methods in place to build, manage, and evaluate their networks. We will also continue to monitor enrollee complaints for access concerns.

For plan years 2019 and later, HHS proposed to further expand the role of States in the QHP certification process for FFEs, including FFEs where the State performs plan management functions. Specifically, we proposed to defer to States for additional review

[88] *https://www.regtap.info/uploads/library/QHP_RateOutlier_FAQ_5CR_071017.pdf.*

[89] This review generally identifies rates that are relatively low compared to other QHP rates in the same rating area. The identification of a QHP rate as an outlier does not necessarily indicate inappropriate rate development; instead, this information helps inform the determination of whether certifying the QHP to be offered on the Exchange would be in the interest of consumers.

[90] Recognition of Entities for the Accreditation of Qualified Health Plans 77 FR 70163 (November 23, 2012) and Approval of an Application by the Accreditation Association for Ambulatory Health Care (AAAHC) To Be a Recognized Accrediting Entity for the Accreditation of Qualified Health Plans 78 FR 77470 (December 23, 2013).

areas, including accreditation requirements at § 156.275, compliance reviews at § 156.715, minimum geographic area of the plan's service area at § 155.1055, and quality improvement strategy reporting at § 156.1130, if feasible and appropriate. In the proposed rule, we stated that we believed States currently perform reviews in these areas that are duplicative of the Federal reviews for QHP certification. As a result, we did not believe this policy would require States to undertake additional reviews or change existing reviews to match the Federal standards for QHPs. We are not finalizing the proposal to defer to States for reviews in these four areas.

Comment: Some commenters supported the proposal to defer the additional review areas of accreditation, minimum geographic area of the plan's service area, compliance reviews, and quality improvement strategy reporting to States for purpose of QHP certification, while some commenters—including some States—opposed the proposal, citing lack of State resources, insufficient staff, and the possibility of increased costs.

Response: We are not finalizing as proposed the deferral to States for the review of service area; accreditation; compliance review—which in this context we interpreted to be review of an issuer's organizational chart and compliance plan; and quality improvement strategy reporting. Based on comments received, we understand that States presently lack resources, including staffing resources, to conduct these reviews. We are less concerned about the potential for Federal reviews to impose unnecessary additional burden on issuers, given information from States and commenters that not all States currently perform these reviews. Our proposal was intended to eliminate duplication in reviews, not to compel States to take on reviews that they are not already performing.

b. QHP Issuer Participation Standards

Section 156.200 sets forth many of the standards a plan must meet to be certified as a QHP. We proposed to amend paragraph (b)(2) to add a cross reference to proposed § 155.706 to align with other changes made throughout this final rule regarding changes to SHOP. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule. We are finalizing the change as proposed.

c. Additional Standards Specific to SHOP for Plan Years Beginning Prior to January 1, 2018 (§ 156.285)

As discussed in the following section, we proposed and are finalizing a modification to the regulatory requirements regarding additional standards specific to SHOP for plan years beginning on or after January 1, 2018 and are introducing those requirements in a new § 156.286. To reflect the proposal that the requirements currently in § 156.285 would apply only for plan years beginning before January 1, 2018, we proposed to amend the heading of § 156.285 and add paragraph (f), to state that the section would only apply for plan years that begin prior to January 1, 2018. We discuss the new standards applicable for plan years beginning on or after January 1, 2018 in the following section. These changes will be effective on the effective date of the final rule.

Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule; we are finalizing these policies as proposed.

d. Additional Standards Specific to SHOP for Plan Years Beginning on or After January 1, 2018 (§ 156.286)

As discussed above, we proposed to make § 156.285, which describes the requirements on QHP issuers participating in SHOPs to accept enrollment and payment information from a SHOP on behalf of an employer or enrollee applicable only for plan years beginning prior to January 1, 2018, and to modify the additional standards specific to QHP issuers participating in SHOPs applicable for plan years beginning on or after January 1, 2018, through the introduction of a new § 156.286. We proposed that new § 156.286 would include only those standards that have been applicable under § 156.285 that would continue to apply to the SHOPs under the proposed approach discussed earlier in this preamble, with minor modifications and clarifications.

We proposed to retain § 156.285(a) as § 156.286(a). However, we proposed to require issuers to accept payment not only from the SHOP, but from a qualified employer or enrollee or a SHOP, to reflect the proposal that a SHOP would not be required to process enrollments and payments. We also proposed not to include the requirement currently in § 156.285(a)(4)(ii), which prohibits issuers in FF–SHOPs from using average enrollee premiums, as the FF–SHOPs and SBE–FPs for SHOP, would no longer be involved in premium payments. For the same reason, we also proposed a narrower version of § 156.285(b) as § 156.286(b), requiring only that issuers adhere to the enrollment periods and processes established by the SHOP consistent with § 155.726, and establish uniform enrollment timelines and processes for qualified employers and group members. We also proposed in § 156.286(c) to include only those requirements from § 156.285(c) that do not relate to the payment and enrollment processes that we have proposed would no longer be required.

We proposed not to include a paragraph mirroring paragraph (d) of § 156.285. This reflects our proposal to remove the requirements contained in current § 155.735, and generally not to impose coverage related timelines on issuers of QHPs through the SHOPs for plans beginning on or after January 1, 2018. We proposed to include a paragraph mirroring § 155.285(e) as § 156.286(d).

Finally, under our proposed and finalized approach, SHOPs will no longer be required to provide employee enrollment functionality. When enrollments are completed by working with SHOP issuers or SHOP-registered agents or brokers, which will be the case for FF–SHOPs, it may not always be immediately apparent to the issuer whether the enrollment is through the SHOP, and whether it is part of an employer's offering a choice of plans. To ensure that issuers offering QHPs through a SHOP do so in a manner that is consistent with our new interpretation of the SHOP provisions of the statute, we proposed to add new paragraphs (e) and (f) in § 156.286. These will require that QHP issuers offering a QHP through the SHOP accept enrollments from groups in accordance with the employer choice policies applicable to the SHOP under § 155.706(b)(3), that they maintain processes sufficient to identify whether a group market enrollment is an enrollment through the SHOP, and they maintain records of SHOP enrollments for a period of 10 years following the enrollment. Proposed paragraph (f) also would require issuers to utilize a uniform enrollment form, as required by section 1311(c)(1)(F) of the PPACA. As noted in the preamble to § 155.716, we intend to update the single employer application to reflect our changes in § 155.731. An issuer will be considered to satisfy this requirement if it uses that application form.

Finally, we proposed in paragraph (g) to state that the requirements contained within § 156.286 are only applicable for

plan years beginning on or after January 1, 2018.

We are finalizing these policies as proposed, with a minor change to § 156.286(a)(1) to reflect that SBEs can continue operating their SHOPs under current practices. These changes are effective as of the effective date of this rule.

Comment: We received a comment that requested clarification on the issuer requirements at § 156.286(a)(1), regarding whether the proposal precluded State Exchanges from directing issuers offering QHPs in their SHOPs to accept payments only from the SHOP.

Response: State Exchanges that do not take advantage of the flexibilities described above for their SHOPs are encouraged to continue operating in a manner consistent with § 156.285, or in a way that best meets the needs of their small group market. The requirements in § 156.286(a)(1) represent minimum SHOP requirements for issuers that would apply to all SHOPs, including those that take advantage of the flexibilities provided for by this final rule, like the FF–SHOPs. We did not intend that the leaner approach to SHOP prohibit State Exchanges from requiring QHP issuers in their SHOPs from accepting payments on behalf of a qualified employer or enrollee from sources other than the SHOP, as the FF–SHOPs had previously done. We have clarified the regulatory text accordingly.

e. Meaningful Difference Standard for Qualified Health Plans in the Federally-Facilitated Exchanges (§ 156.298)

We proposed to remove § 156.298 to eliminate meaningful difference standards for QHPs offered through an FFE or SBE–FP. Under this standard, in order to be certified as a QHP, a plan must be meaningfully different from all other QHPs offered by the same issuer of that plan within a service area and level of coverage in the Exchange. As defined in § 156.298(b), QHPs are considered meaningfully different from other plans if a reasonable consumer would be able to identify one or more material differences among five key characteristics between the plan and other plans to be offered by the same issuer.

This meaningful difference standard was implemented to make it easier for consumers to understand differences between plans, and choose the right plan option for them. However, with fewer issuers participating in the Exchange, and fewer plans for consumers to choose from, we proposed to remove these standards, as we no longer believe the requirement is necessary. We believe removing the meaningful difference standard would encourage plan design innovation, by providing more flexibility to issuers in designing plans, and thus increase plan offerings and choice for consumers.

We are finalizing this policy as proposed.

Comment: While some commenters supported removing the meaningful difference standard, several commenters opposed removing it, stating that the standard helps consumers avoid confusion and improves the consumer shopping experience. Some commenters stated that removing the standard would decrease the comparative value of the data and increase the probability of duplicative QHP offerings, with one commenter stating that removing the standard would encourage a proliferation of plans. One commenter stated that removing the standard could lead to benefit designs aimed to attract healthy enrollees and repel sick enrollees. One commenter recommended that we provide an exception to the meaningful difference standard in cases where a comparison is not feasible, while maintaining the requirement in cases where comparisons are feasible. One commenter supported removing the standard as long as certain conditions outside the scope of this rule were met.

Response: We believe that removing the meaningful difference standard will not substantially increase the number of materially similar plans from the same issuer. Plan selection tools provide consumers with information to distinguish between plans and see similarities or differences. With fewer plans on the Exchanges than in prior years, we believe removing this standard will encourage innovation and increase plan offerings and choice for consumers, the benefits of which would outweigh any potential confusion.

f. Other Considerations

We sought comment on ways in which HHS can foster market-driven programs that can improve the management and costs of care and that provide consumers with quality, person-centered coverage. As we stated in the 2017 and 2018 Payment Notices, we believe that innovative issuer, provider, Exchange, and local programs or strategies can successfully promote and manage care, in a manner that contributes to better health outcomes and lower rates while creating important differentiation opportunities for market participants. We sought comment on ways in which we can facilitate such innovation, and in particular on whether there are regulations or policies in place that we should modify in order to better meet the goals of affordability, quality, and access to care.

We also sought comment on how we may encourage value-based insurance design within the individual and small group markets and ways to support issuers in using cost sharing to incentivize more cost-effective enrollee behavior and higher quality health outcomes, in accordance with section 2713(c) of the PHS Act. Currently, under our rules, issuers have considerable discretion in the design of cost-sharing structures, subject to certain statutory AV requirements, non-discrimination laws and rules,[91] and other applicable law, such as MHPAEA.

We would like to encourage issuers to offer HDHPs that can be paired with a health savings account (HSA) as a cost effective option for enrollees. While the proportion of available HSA-eligible HDHPs has been stable in the FFEs, the percentage of enrollees in HDHPs has decreased slightly over the last 3 years as there are certain technical barriers for issuers in offering HDHPs.[92] We are particularly interested in exploring how to use plan display options on *HealthCare.gov* to promote the availability of HDHPs to applicants, and sought comment on how best to do so.

We are also interested in value-based insurance designs that focus on cost effective drug tiering structures; address overused, higher cost health services; provide innovative network design that incentivizes enrollees to use higher quality care; and promote use of preventive care and wellness services. We solicited comments on how HHS can better encourage these types of plan designs, and whether any existing regulatory provisions or practices discourage such designs.

Comment: Many commenters supported HHS exploring ways to encourage innovation and value-based insurance design. There was general support for HHS to drive towards improved health outcomes and efficient health care delivery. Commenters noted that issuers should be encouraged to

[91] We note that issuers are also subject to Federal civil rights laws, including Title VI of the Civil Rights Act, section 504 of the Rehabilitation Act, the Age Discrimination Act, section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

[92] For instance, the maximum annual limitation on cost sharing established at section 1302(c) of the PPACA is increasing at a faster rate than the maximum out of pocket cost limits for HDHPs under section 223 of the Code. Therefore, a plan that utilizes the maximum annual limitation on cost sharing under the PPACA would not meet the requirements to be an HDHP under the Code that could be paired with an HSA.

engage in value-based insurance design that utilizes clinical effectiveness research and drives consumers to efficient high quality providers. Commenters questioned how services would be deemed high-value and cautioned against disincentivizing consumers from seeking preventive and wellness care, and care for chronic conditions. Commenters suggested that HHS seek public comment on services that are high value or leverage data from comparative effectiveness research to identify low-value services.

Commenters generally supported increasing transparency of health information, but cautioned that consumers would need education and tools in order to make information useful. Some requested that additional information be incorporated into *HealthCare.gov*, plan selection tools, the Summary of Benefits and Coverage, or the out-of-pocket estimator tool.

Others suggested that specific alternative payment options be allowable, such as reference pricing or allowing issuers the flexibility to apply the annual limitation on cost sharing to accumulate differently in tiered networks.

Comments were mixed regarding HSA-eligible HDHPs. Many commenters cautioned that HDHPs do not meet the needs of low-income consumers and urged that HHS provide appropriate explanations and ensure there are consumer protections to make sure consumers make appropriate plan selections. Others noted that *HealthCare.gov* should provide more information on how to use HDHPs and how to set up HSAs. Others commented that promoting HDHPs would require training of Navigators and call center staff to handle additional questions. Some noted that *HealthCare.gov* support should not answer questions more appropriate for HSA custodians.

Commenters noted the statutory and regulatory issues with offering HSA-eligible HDHPs on Exchanges, including the misalignment of annual limitations on cost sharing between the PPACA and the Code. Others requested that the IRS expand preventive care safe harbors under section 223(c)(2)(C) of the Code to include services and benefits related to the management of chronic conditions and medications.

One commenter suggested that HHS provide subsidies in the form of HSA contributions instead of cost-sharing reductions. Other commenters offered additional responses related to drug pricing, encouraging HHS to prioritize the transparency of drug pricing in general, and other health care costs. Others noted that with the removal of standardized options, HHS should consider other ways to incentivize issuers to offer at least some QHPs with prescription drugs not subject to the deductible. Other commenters noted specific examples where issuers were waiving cost sharing for high value prescription drugs, such as those to treat high blood pressure. Others suggested that drug rebates could be available to consumers at the point of sale. Additional commenters expressed concerns about changes to the 340B drug discount program.

Response: We appreciate these comments and will take them under consideration. We note that the Treasury Department and the IRS have jurisdiction over HSAs and HSA-eligible HDHPs under section 223 of the Code.

4. Standards for Downstream and Delegated Entities (§ 156.340)

Section 156.340 sets forth the responsibilities of a QHP issuer and its applicable downstream entities. We proposed to amend paragraph (a)(2) to add a cross reference to proposed § 155.706 to align with other changes made throughout this rule regarding SHOP. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

We are finalizing the change as proposed.

5. Eligibility and Enrollment Standards for Qualified Health Plan Issuers on State-Based Exchanges on the Federal Platform (§ 156.350)

Section 156.350 describes the eligibility and enrollment standards for issuers that offer QHP coverage in the SBE–FPs. Currently, § 156.350(a)(1) and (2) state that for a QHP issuer to participate in an SBE–FP for SHOP, it must comply with the requirements at § 156.285(a)(4)(ii) and § 156.285(c)(5) and (c)(8)(iii), respectively. However, as discussed elsewhere in this final rule, to align with our proposal regarding the SHOPs, we proposed, and are finalizing, that these referenced requirements at § 156.285 would not be applicable for plan years beginning on or after January 1, 2018, effective on the effective date of this rule. Therefore, we proposed to amend § 156.350(a)(1) and (a)(2) to specify that they only apply through plan years beginning prior to January 1, 2018.

Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule. We are finalizing the changes as proposed.

6. Minimum Essential Coverage

a. Other Coverage That Qualifies as Minimum Essential Coverage (§ 156.602)

A CHIP program is a type of government-sponsored coverage, defined under title XXI of the Act that provides low-cost health coverage to children in low-income families that do not otherwise have health coverage. States may be eligible to receive Federal funds to initiate and expand such programs. A CHIP buy-in program, a ''full pay'' option where a covered family pays the full premium typically without any Federal or State assistance, often provides similar or identical benefits as the State's CHIP program under title XXI of the Act (the title XXI CHIP program) for children in families that do not financially qualify for the title XXI CHIP program.[93] We proposed to amend § 156.602 to specifically designate as MEC CHIP buy-in programs that provide identical coverage to that title XXI CHIP program pursuant to the Secretary's authority under section 5000A(f)(1)(E) of the Code. We sought comment on whether CHIP buy-in programs that provide greater coverage than the title XXI CHIP program should be categorically designated as MEC. Finally, we sought comment on whether other types of government-sponsored buy-in programs, such as Medicaid buy-in programs, should be categorically designated as MEC. We are not finalizing the policy to categorically designate as MEC CHIP buy-in programs that provide identical or greater coverage to the title XXI CHIP program.

Comment: Some commenters supported categorically designating as MEC CHIP buy-in programs that provide identical or greater coverage to the title XXI CHIP program because the categorical designation would drive down premiums and out-of-pocket costs for full-pay families, as well as eliminate deductibles. In addition, the change would permit consumers to move between the title XXI CHIP program and CHIP buy-in programs without experiencing a change in benefits. Other commenters expressed concern that a categorical designation would prevent HHS from verifying that the benefits of a CHIP buy-in program are identical to the title XXI CHIP program which could lead to adverse selection in the individual market or erosion of CHIP benefits.

[93] Under IRS Notice 2015–37, individuals who may enroll in a CHIP buy-in program designated as MEC are eligible for MEC under the CHIP buy-in program for purposes of the premium tax credit under section 36B of the Code only if they are enrolled in the program.

Response: Following the publication of the proposed rule, Congress designated qualified CHIP look-alike plans as MEC. Section 5000A(f)(1)(A)(iii) of the Code, as amended by section 3002(g)(2)(A) of the HEALTHY KIDS Act, specifically designates CHIP look-alike plans as MEC. Section 2107 of the Social Security Act, as amended by section 3002(g)(1) of the HEALTHY KIDS Act, defines a CHIP look-alike plan as a CHIP buy-in program that provides ''benefits that are at least identical to the benefits provided'' by the title XXI CHIP program.[94] Therefore, we are not finalizing the proposed changes to § 156.602 since CHIP look-alike plans are now statutorily designated as MEC.

However, because the amendment does not designate all CHIP buy-in programs as MEC, we recognize that States and enrollees may have questions regarding whether a particular State's CHIP buy-in program is MEC. To provide States and enrollees with certainty as to whether their coverage constitutes MEC, States will have the option to verify with HHS that their CHIP buy-in program meets the definition of a CHIP look-alike plan. A State may verify that a CHIP buy-in program is a qualified CHIP look-alike plan by submitting documentation to HHS via the Health Insurance Oversight System (HIOS) (as described in section V of the October 31, 2013 Insurance Bulletin[95]) that provides a detailed summary of the coverage provided by the CHIP buy-in program and the title XXI CHIP program. Upon review and comparison of the coverage, if HHS determines that the CHIP buy-in program provides at least the same coverage as the title XXI CHIP program, then HHS will confirm that the CHIP buy-in program is a CHIP look-alike plan. If HHS determines that the CHIP buy-in program does not provide at least the same coverage as the title XXI CHIP program, then the plan sponsor may work with HHS to modify the CHIP buy-in program to offer at least the same coverage as the title XXI CHIP program. In the alternative, the plan sponsor may apply for MEC recognition through the process outlined in § 156.604 under which HHS will evaluate whether the CHIP buy-in program complies with ''substantially all'' of the provisions of title I of the PPACA that apply to non-grandfathered individual health insurance coverage.

CHIP buy-in plans that are not CHIP look-alike plans may also continue to receive MEC recognition through the MEC application process if the State can demonstrate that the coverage meets substantially all the requirements of title I of the PPACA pertaining to non-grandfathered, individual health insurance coverage.

Comment: One commenter stated that States should have the flexibility to offer a Medicaid buy-in program in an effort to stabilize the market and increase competition.

Response: While we are not finalizing that Medicaid buy-in programs are designated as MEC, HHS invites all States to apply for their Medicaid buy-in programs to be recognized as MEC in the process outlined in § 156.604.

b. Requirements for Recognition as Minimum Essential Coverage for Types of Coverage Not Otherwise Designated Minimum Essential Coverage in the Statute or This Subpart (§ 156.604)

Under § 156.604, the Secretary may recognize coverage as MEC provided HHS determines that the plan meets substantially all the requirements of title I of the PPACA pertaining to non-grandfathered, individual health insurance coverage (the ''substantially all'' standard). In the proposed rule, we sought comment on whether HHS should create a new standard of review under which CHIP buy-in programs must ''substantially resemble'' the title XXI CHIP program under title XXI to qualify as MEC under § 156.604. We are not finalizing a substantially resemble standard of review.

Comment: One commenter stated that the ''substantially resemble'' standard is more meaningful to State CHIP administrators than the ''substantially all'' standard and would allow for more reasonable evaluation by HHS of each individual buy-in program. Some commenters stated the ''substantially resemble'' standard must be better defined and delineated to provide clear guidelines on what constitutes a qualifying buy-in program. The commenters stated that, without clarity, there would be confusion and States could be more arbitrary in their decision-making for the scope of benefits. Other commenters stated that the CHIP buy-in programs should be subject to the ''substantially all'' standard that applies to other MEC applicants. To provide a lesser standard to CHIP buy-in programs could result in fewer benefits for the children in those programs.

Response: After reviewing these comments, we agree that it is important for HHS to provide clear standards of review for the MEC application process and to ensure that enrollees in these programs obtain benefits that are similar to the benefits in PPACA compliant coverage. We are not finalizing a ''substantially resemble'' standard. As described in the previous section, section 5000A(f)(1)(A)(iii) of the Code, as amended by section 3002(g)(2)(A) of the HEALTHY KIDS Act, specifically designates CHIP buy-in programs that provide benefits that are at least identical to the benefits provided by the title XXI CHIP program as MEC. CHIP buy-in programs that do not provide identical or greater benefits than what is provided in the State's title XXI program will be subject to the ''substantially all'' standard for MEC recognition.

7. Quality Rating System (§ 156.1120)

We recognize that social risk factors play a major role in health, and one of our core objectives is to improve patients' outcomes including reducing health disparities. In addition, we seek to ensure that the quality of care furnished by providers and health plans is assessed as fairly and accurately as possible under HHS quality reporting programs, including the Quality Rating System established under section 1311(c)(3) of the PPACA, while helping to ensure that individuals and populations receive high quality, person-centered care. In response to several comments we received from the Request for Information, we continue to assess ways to reduce burden and promote State flexibility in the implementation of all statutorily required Exchange quality programs, including the Quality Rating System, and we continue to prioritize strategies to improve the value for consumers. We received many comments as part of the annual Quality Rating System Call Letter process in response to our request for public comment on whether we should account for social risk factors in the Quality Rating System, which provides quality ratings (or star ratings from 1 to 5 stars) that account for member experience, medical care and health plan administration for QHPs, offered through an Exchange. We did not propose amendments to the Quality Rating System regulations in the proposed rule.

We sought comment as part of this rulemaking on types of social risk factors that may be most appropriate, as well as the methods to account for social risk factors for QHP issuer quality

[94] Extension of Continuing Appropriations Act, 2018; HEALTHY KIDS Act; Federal Register Printing Savings Act of 2017, Public Law 115–120, 101 (2018).

[95] *See* CCIIO Sub-regulatory Guidance: Process for Obtaining Recognition as Minimum Essential Coverage (October 31, 2013). Available at *http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/mec-guidance-10-31-2013.pdf.*

reporting. Examples of social risk factors include: Low income subsidy; race and ethnicity; and geographic area of residence. Approaches to account for social risk factors include stratifying measure scores or risk adjustment of a particular measure. We sought comment on which social risk factors could be used alone or in combination, current data sources where this information would be available, and whether other data should be collected to better capture the effects of social risk.

Comment: Although many commenters expressed that accounting for social risk factors in measuring performance is contentious and challenging, there was overall support for the need to address socioeconomic factors that can affect quality in reporting of quality data and for CMS to closely monitor the ongoing work of the Office of the Assistant Secretary for Planning and Evaluation and the National Quality Forum regarding socioeconomic status in health outcomes and quality. Commenters encouraged HHS to increase opportunities for collaboration across all HHS quality rating programs, including the Exchange Quality Rating System, Medicare Advantage and Medicaid health plans and provided some recommendations on methods of accounting for social risk factors in the Quality Rating System. Some commenters did not support adjusting for socioeconomic status because they believe that could be counter-productive and potentially signal an expectation, even acceptance, of lower outcomes for financially disadvantaged consumers.

Commenters provided examples of types of social risk factors and combination of factors that would most appropriately account for QHP issuer quality reporting and clarified which data is readily collected by Exchanges. The types of social risk factors mentioned included patient level data about race and ethnicity; income level; preferred language; disability status; sexual orientation and gender identity; psychological and behavioral status; alcohol and tobacco use; residential address; low-income subsidy eligibility status; and per the recommendations of the National Academies of Sciences, Engineering, and Medicine: Health and Medicine Division,[96] the systematic collection of data in the following domains: Depression, education, financial resource strain, intimate partner violence, physical activity, social connections and social isolation, stress, housing status, insurance status, employment, transportation, incarceration and refugee status. Commenters also provided support for stratifying measure data and not risk adjusting the Quality Rating System for social risk factors, to help plans identify and distinguish efforts to improve quality from efforts to reduce disparities. Commenters stated that stratifying measure results by socioeconomic status of patients within affected measures would highlight disparities, showing plans which subpopulations among their enrollees most need targeted quality improvement efforts.

Response: We appreciate the comments, and will take them under consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the Quality Rating System. We will continue to collaborate with the Office of the Assistant Secretary for Planning and Evaluation, the National Quality Forum, and with issuer, provider, and enrollee stakeholders to assess methods for the collection and application of social risk factor information for future years of the Quality Rating System program.

8. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (§ 156.1230)

We proposed to amend paragraph (b)(2) of § 156.1230 to conform with the proposed amendments to § 155.221. The change requires that, prior to a QHP issuer's internet website being used to complete a QHP selection, the QHP issuer must engage a third-party entity in accordance with § 155.221 to demonstrate operational readiness and compliance with applicable requirements. For a discussion of the provisions of this final rule related to third-party entities performing operational readiness reviews, please see the preamble to § 155.221. We are finalizing the amendments to § 156.1230 as proposed.

Comment: One commenter requested clarification on whether the proposed § 156.1230(b)(2) is meant to apply only when an Exchange delegates the enrollment function to plans operating in the individual market.

Response: No FFE has delegated the enrollment function to plans operating in the individual market. Notwithstanding this, § 156.1230(b) permits QHPs in FFEs to directly enroll individual market applicants in a manner that is considered through the Exchange, to the extent permitted by applicable State law. Paragraph (b)(2) applies in all circumstances where an issuer participating in an FFE performs such a direct enrollment. A QHP issuer participating in an SBE–FP may also, under § 156.350, directly enroll applicants, and must comply with the requirements in § 156.1230(b)(2) as if it were an issuer of QHPs on an FFE when using the direct enrollment pathway.

F. Part 157—Employer Interactions With Exchanges and SHOP Participation

1. Qualified Employer Participation Process in a SHOP for Plan Years Beginning Prior to January 1, 2018 (§ 157.205)

As discussed in the following section, we proposed to modify the regulatory requirements regarding the qualified employer participation process in a SHOP for plan years beginning on or after January 1, 2018 and to introduce those requirements in a new § 157.206. To reflect the proposal that the requirements currently in § 157.205 would apply only for plan years beginning before January 1, 2018, we proposed to amend the heading of § 157.205 and add paragraph (h), to state that the section would apply only for plan years that begin prior to January 1, 2018.

Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule. We are finalizing these policies as proposed. These changes will be effective on the effective date of this rule.

2. Qualified Employer Participation Process in a SHOP for Plan Years Beginning on or After January 1, 2018 (§ 157.206)

Section 157.205 describes requirements for participating SHOP employers. To reflect the proposal to allow SHOPs to operate in a leaner fashion, we proposed several changes to the requirements related to qualified employer participation process in a SHOP for plan years beginning on or after January 1, 2018, and proposed to introduce these requirements in § 157.206. With the exception of the proposed changes to the process described here, the process will remain the same as in § 157.205. The proposals described in this section will be effective on the effective date of the final rule.

Paragraph (d) of § 157.205 requires a qualified employer to submit any contribution towards the premiums of any qualified employee according to the standards and processes described in § 155.705. Because we proposed that the requirements in § 155.705 regarding

[96] IOM (Institute of Medicine). 2014. Capturing social and behavioral domains and measures in electronic health records: Phase 2. Washington, DC: The National Academies Press. *https://www.nap.edu/read/18951/chapter/1.*

employer contribution methods will not apply for plan years beginning on or after January 1, 2018, we also proposed that the requirement in § 157.705(d) will not apply for those plan years.

Paragraph (e)(1) of § 157.205 describes obligations of qualified employers to employees hired outside of the initial or annual open enrollment periods. We proposed in § 157.206(d) that qualified employers must provide employees hired outside of the initial or annual open enrollment period with information about the enrollment process. We proposed that the requirement in paragraph (e)(1) of § 157.705, which requires qualified employers to provide these employees with an enrollment period in accordance with § 155.725(g), would not be included in § 157.206, as the requirement in § 155.725(g) will not be applicable for plan years beginning on or after January 1, 2018. We also proposed that the requirement in § 157.205(e)(2) to provide information about the enrollment process in accordance with § 155.725 would not apply for plan years beginning on or after January 1, 2018 to reflect that the process provided for in many of the provisions in § 155.725 will not apply for those plan years.

We also proposed that the requirements in § 157.205(f) regarding the process for notifying the SHOP in the event the eligibility status of an employee, or employee's dependent has changed would not apply for plan years beginning on or after January 1, 2018. Under the approach finalized in this rule for plan years beginning on or after January 1, 2018, SHOPs will not be required to process employee enrollment, so there will be no reason for all qualified employers to provide such information.

Further, we proposed that the requirement in § 157.205(g) that qualified employers adhere to the annual employer election period under § 155.725(c) would not apply for plan years beginning on or after January 1, 2018. Elsewhere, we finalized that the annual employer election period provision in § 155.725(c) will not apply for those plan years, and this change reflects that removal.

Finally, we proposed in paragraph (e) of § 157.206 to include new requirements for qualified employers reflective of the proposed approach for SHOPs generally. First, since we proposed in § 155.716(f) that an employer's determination of eligibility to participate in the SHOP remains valid until the employer makes a change that could end its eligibility under § 155.710(b), we proposed in § 157.205(e)(1) that employers must submit a new application to the SHOP if the employer makes a change that could end its eligibility under § 155.710 or withdraw from participation in the SHOP. Second, because under the changes we have finalized elsewhere in this rule, SHOPs will not be required to process group enrollments, and therefore will not necessarily communicate with QHP issuers about employer eligibility determinations, we proposed to require employers to notify the QHP issuer of an unfavorable eligibility determination. However, we proposed that the employer be required to provide the notification within 5 business days of the end of any applicable appeal process under § 155.741. Specifically, the end of the appeal process could occur when the time to file an appeal lapses without an appeal being filed, when the appeal is rejected or dismissed, or when the appeal process concludes with an adjudication by the appeals entity, as applicable. We also proposed in paragraph (e)(3) to describe the employer's obligations regarding loss of eligibility to participate in a SHOP or termination of enrollment or coverage through the SHOP. Given that under the approach finalized in this rule there will not necessarily be communication between the SHOP and a participating QHP issuer regarding employer eligibility, enrollment, or terminations, there may be no way for the SHOP to notify an issuer in the event an employer becomes ineligible to participate in SHOP. Therefore, we proposed to add paragraph (e)(3) to require employers to notify an issuer of a loss of eligibility to participate in SHOP, or a desire to terminate SHOP enrollment or coverage.

We proposed in paragraph (f) of § 157.205 that the section would apply for plan years beginning on or after January 1, 2018, only.

Substantive comments relating to our proposals regarding SHOP are addressed in section III.D.9 of this rule, as well as in the preamble discussing §§ 156.285 and 156.286. We are finalizing new § 157.206 as proposed, with minor changes to paragraphs (e)(2) and (e)(3). As noted in the preamble to the SHOP sections in part 155, State Exchanges are encouraged to continue to operate their SHOPs as they do today, or design a SHOP within the bounds of the flexibilities being finalized within this rule. To ensure that SHOPs can continue to operate as they do today, we are providing flexibility to employers to allow them not to notify issuers of determinations of ineligibility to participate in the SHOP or their desire to terminate their participation in the SHOP in cases where the SHOP has notified the issuer. We are making this change to recognize that State-based SHOPs may continue to provide these notifications, in which case employers should not be required to provide duplicative notifications. Section 156.206 will become effective as of the effective date of the final rule.

G. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Reporting of Federal and State Taxes (§ 158.162)

Section 2718 of the PHS Act requires that Federal and State taxes be reported, but that such amounts be excluded from premium revenue when calculating an issuer's MLR and accompanying rebates. However, the statute does not define what is included in Federal and State taxes. The MLR December 1, 2010, interim final rule (75 FR 74864) interprets this language and broadly describes Federal and State taxes that must be reported but are excluded from premiums in the MLR and rebate calculations, and Federal and State taxes that must be reported and are not excluded from premiums in MLR and rebate calculations. In order to provide consistency and clarity for MLR reporting, HHS amended § 158.162 in the 2016 Payment Notice (80 FR 10750) to specify that all issuers must include employment taxes in earned premiums and must not deduct such taxes in the MLR and rebate calculations starting with the 2016 MLR reporting year.

However, we received several comments in favor of allowing issuers to deduct such taxes from these calculations in response to the Request for Information. Therefore, in the proposed rule, we invited comments on whether, in order to encourage issuer participation and competition in the markets, HHS should revise paragraph (a)(2) and paragraph (b)(2)(iv) of § 158.162 to allow all issuers to deduct Federal and State employment taxes from premiums in their MLR and rebate calculations, starting with the 2017 MLR reporting year for reports to be filed by July 31, 2018.

We solicited comments on this approach from all stakeholders, including on whether we should instead amend the MLR regulations to collect the employment tax data separately from other tax data as an informational item on the MLR Annual Reporting Form to gather data to inform a decision regarding whether to amend the regulation for future years, and whether changing the treatment of employment

taxes would be likely to help improve market stability and competition.

Comment: We received almost an equal number of comments opposing and supporting exclusion of Federal and State employment taxes from earned premium in the MLR and rebate calculations. Some who commented in opposition noted that modifying the treatment of employment taxes would contradict HHS's previous decision. Other commenters expressed concern that such policy would raise MLRs without producing greater value for consumers and would undermine consumer protections. Several commenters stated that it is the uncertainty and the changes to the MLR reporting parameters, rather than employment taxes that negatively affect market stability. In contrast, several other commenters stated that excluding employment taxes would improve market stability and provide incentives for issuers to enter or remain in the market. Some commenters stated that the PPACA provides for the exclusion of taxes from the MLR calculation and that including employment taxes is inconsistent with the treatment of other taxes. Lastly, a number of commenters recommended that HHS gather additional information on the impact of excluding employment taxes on consumers and issuers before making changes to the current policy. One commenter encouraged HHS to consider the impact on issuers providing coverage on- versus off-Exchanges, as well as the potential double-counting that may occur between excluding employment taxes from premium while also including them in quality improvement activity (QIA) expenses.

Response: HHS appreciates the comments submitted regarding the treatment of Federal and State employment taxes in the MLR and rebate calculations. We share the concern of some commenters that reversing the policy on the treatment of employment taxes only 1 year after the policy became effective could contribute to instability. We also continue to disagree that the PPACA unambiguously requires exclusion of employment taxes from the MLR and rebate calculations. However, it is our objective to explore and pursue all policy solutions that may help stabilize the health insurance market. Therefore, after reviewing the comments and recommendations, HHS intends to gather data to help analyze the potential impact on consumers and issuers that would result from excluding Federal and State employment taxes from earned premium in the MLR and rebate calculations, and perform additional data analysis to inform whether a modification to the current policy would be appropriate. Specifically, while issuers already report the employment tax amounts together with other taxes on the MLR reporting form, HHS intends to propose changes to the MLR Annual Reporting Form to include a separate line that will show these tax amounts for each issuer. This will provide HHS with more up-to-date and consistent data on employment taxes to more precisely estimate how potential modifications to the current policy may affect issuers and consumers and to determine whether such modifications would likely improve market stability.

2. Allocation of Expenses (§ 158.170)

For a discussion of the proposed amendment to § 158.170(b) regarding the description of the allocation method for quality improvement activity (QIA) expenses and a summary of the comments received and responses provided, please see the preamble to § 158.221. We are finalizing the change as proposed.

3. Formula for Calculating an Issuer's Medical Loss Ratio (§ 158.221)

We proposed amending § 158.221 by adding new paragraph (b)(8) to provide issuers with an option to report quality improvement activity (QIA) expenses as a single fixed percentage of premium amount starting with the 2017 MLR reporting year (for reports to be filed by July 31, 2018). We also proposed conforming amendments to § 158.170(b) (Allocation of expenses) to recognize the new proposed option for reporting QIA expenses.

Consistent with the NAIC's recommendation to HHS,[97] the MLR interim final rule, published on December 1, 2010 (75 FR 74863), allows issuers to include in the MLR numerator expenditures for five categories of activities that improve health care quality. Accordingly, issuers are currently required to report QIA expenditures in alignment with the five separate categories codified in § 158.150(b)(2)(i)–(v). Additionally, § 158.170 requires issuers to use and disclose specific allocation methods to report expenses, including QIA expenditures.

In the course of conducting the MLR audits, HHS observed that the current MLR regulations require a substantial effort by issuers to accurately identify, track and report QIA expenses. HHS has also observed that, between 2011 and 2015, issuers that did report QIA expenses have reported spending, on average, a consistent percentage of premium on total QIA: approximately 0.7 percent in 2011, and 0.8 percent in 2012 through 2015.

Given issuers' relatively low and consistent reported expenditures on QIA and the significant burden associated with identifying, tracking and reporting these expenditures, we proposed adding § 158.221(b)(8) to permit issuers an option to report on their MLR reporting form a single QIA amount equal to 0.8 percent of earned premium in the relevant State and market, in lieu of tracking and reporting the issuer's actual expenditures for QIA, as defined in § 158.150 and § 158.151. The accompanying proposed amendments to § 158.170(b) would require issuers that elect the option to include 0.8 percent of earned premium for QIA expenses to indicate as such when describing the allocation method used for QIA expenses. Issuers that spend more than 0.8 percent of earned premium on QIA would have the option to report the total actual, higher amount spent and, if choosing this option, would have to report QIA in the five categories described in § 158.150(b)(2)(i)–(v), as well as comply with the allocation of expenses requirements established under § 158.170.

We are finalizing this policy as proposed, except that, in response to comments, we are specifying, as described below, how the optional QIA reporting method may be used across affiliated issuers, markets, and years.

Comment: We received comments from consumer and patient advocacy groups, health insurance issuers, States, and individuals regarding the proposal to provide a standardized option to report QIA. Most commenters opposing the proposal stated that the current QIA requirements motivate issuers to invest in improving the health and well-being of consumers, and therefore allowing issuers who spend nothing on QIA to take a standardized credit for QIA would disincentivize issuers from making such investments. Many commenters stated that by giving issuers credit for expenses that issuers may not actually incur, the proposal would result in consumers receiving coverage of a lower value. Some commenters expressed concern that the 0.8 percent standardized option would further provide a competitive advantage to issuers that get credit without investing

[97] National Association of Insurance Commissioners—Model Regulation Service, Regulation for Uniform Definitions and Standardized Methodologies for Calculation of the Medical Loss Ratio for Plan Years 2011, 2012 and 2013 per Section 2718(b) of the Public Health Service Act (Oct 27, 2010), available at *http://www.naic.org/documents/committees_ex_mlr_reg_asadopted.pdf.*

in QIA. Many commenters stated that State regulators and consumers are interested in knowing how much and what types of innovative QIA are being implemented, and would lose access to this information under the proposal. These commenters were also concerned that reduced accountability would adversely affect the integrity of the MLR program. One commenter pointed out that premiums tend to increase faster than non-medical expenses so using a flat 0.8 percent may overstate QIA in the future. Most commenters who supported the proposal stated that the current process for identifying, tracking and reporting QIA expenses is burdensome, time consuming and costly. Some commenters indicated that it is hard for issuers to segregate QIA expenses since QIA is ingrained throughout issuers' activities and the current process requires issuers to track individual employees' time spent on a specific task. A few commenters suggested raising the standardized credit to 1.0 percent of premiums, some stated that 0.8 percent would be appropriate, while others contended that 0.8 percent would be excessive. One commenter requested that HHS clarify whether issuers must make an election to use the optional QIA reporting method prior to the plan year; whether it must be elected for a minimum fixed period of years; and the issuer, State, and market aggregation level(s) to which the election applies. One commenter recommended that issuers be allowed to retroactively change the QIA reporting method with respect to the 2 prior years included in the MLR calculation, while another commenter recommended that issuers be allowed to elect the standardized QIA option for only some of their markets. In contrast, another commenter expressed concern that such approach could lead to inadvertent or intentional double-counting, particularly for those issuers that incur QIA expenses at the holding group level, and recommended that HHS require a consistent reporting methodology across all markets at the holding group level and for a minimum of 3 consecutive years. Several commenters requested inclusion of certain other activities in QIA, which we note is beyond the scope of the amendments proposed in the proposed rule.

Response: We reviewed each of the comments and recommendations and are finalizing the amendments as proposed with the following modification. In response to commenters' request for clarification regarding the application of the new QIA reporting option, and in order to address commenters' concerns regarding the impact of the new QIA reporting option on the integrity of the MLR program, we are specifying that issuers and their affiliates that elect the standardized QIA reporting option must apply it consistently across all of their States and markets that are subject to the MLR requirements in section 2718 of the Public Health Service Act. Further, similarly to some other optional MLR reporting provisions,[98] issuers and their affiliates that elect the standardized QIA reporting option must apply this reporting method for a minimum of 3 consecutive reporting years. In addition, we will require all affiliated issuers to elect the same QIA reporting method. These provisions will ensure that the new QIA reporting option is appropriately utilized by issuers to simplify reporting, rather than to inflate the MLR based on the experience of a particular year. Further, in the course of conducting the MLR audits, HHS observed that QIA initiatives are often developed and administered at the parent company level and the costs are then prorated down to each issuer, State, and market segment using complex allocation methods. Therefore, the requirement that the new QIA reporting option be applied in a consistent manner across all States, relevant markets, and affiliates will additionally eliminate gaming incentives for companies to use the standardized 0.8 percent of premium QIA amount for some of their issuers, States, or markets and simultaneously maximize the allocation of the actual QIA costs to their other issuers, States, or markets. This approach is also consistent with the fact that the 0.8 percent of premium threshold was identified based on the average across all issuers, States, and markets. We note that the new QIA reporting method is optional, and does not prevent issuers from continuing to allocate and benefit from reporting the actual QIA expenses for each State and market. While we acknowledge commenters' concerns that the standardized QIA reporting option may in some cases give issuers credit for activities that they do not perform, we note that issuers also have financial incentives to improve the health of their enrollees because healthier populations incur lower medical costs, and reducing the administrative burden associated with tracking QIA will free up funds that issuers can invest in QIA. Additionally, while we recognize that there is variation in QIA spending between different issuers, we continue to believe that 0.8 of earned premium is appropriate based on the average of MLR data over 2011–2015, and that a single nationwide percentage provides the benefit of simplicity and reduces burdens associated with tracking and reporting QIA expenses. As noted previously, issuers will continue to have the option to report the actual expenditures and therefore will retain the ability to take full credit if these expenditures exceed 0.8 percent of premium. With respect to commenters' concern that QIA expenditures may not grow proportionately to premium and that 0.8 percent may overstate issuers' average QIA expenditures in the future, as well as commenters' concern that they may lose access to the detailed QIA data, we also note that presently, issuers continue to report to States QIA data that in some respects are even more detailed than the data previously collected by HHS. Therefore, the public and States retain the ability to access this type of information. In addition, HHS will monitor QIA reporting and review available data, and may modify the QIA reporting policy in the future if HHS determines it to be necessary. Finally, we note this change will also help level the playing field among issuers, since many issuers likely do engage in QIA but currently forego reporting because the burden of analyzing, documenting, tracking, allocating, and reporting QIA expenses exceeds the benefits for MLR purposes.

[98] Such as the reporting of group health insurance coverage with dual contracts in § 158.120(c).

4. Potential Adjustment to the MLR for a State's Individual Market (Subpart C)

We proposed to amend 45 CFR part 158, subpart C to modify the process and criteria for the Secretary to determine whether to adjust the 80 percent MLR standard in the individual market in a State. Because the majority of comments focused on the broader merits of amending subpart C, rather than on the specific sections, we address all comments after summarizing the proposed amendments to each section.

Section 2718(d) of the PHS Act provides that the Secretary may adjust the MLR standard in the individual market if the Secretary determines it appropriate on account of the volatility of the individual market due to the establishment of Exchanges. The MLR December 1, 2010, interim final rule (75 FR 74864) set forth the framework for a State to request such an adjustment and the process and criteria for the Secretary to determine whether to grant a State's request. Subpart C of 45 CFR part 158 specifies that the adjustment request

must be initiated by the State, the adjustment may be granted for up to 3 years at a time, the information that the State must provide to support its request, and the criteria that HHS may consider in making a determination. It also requires the Secretary to invite public comments on the adjustment requests, allows States to hold optional public hearings, and enables States to request reconsideration of adverse determinations.

Because in the current environment, it generally is not the MLR standard in isolation but rather factors that, taken together, can contribute to instability of the individual market in certain States, the current framework in subpart C restricts the States' ability to obtain adjustments to the MLR standard as part of innovative solutions for stabilizing their individual markets. Therefore, as outlined below, we proposed to make amendments throughout subpart C of part 158 to allow for adjustments to the individual market MLR standard in any State that demonstrates that a lower MLR standard could help stabilize its individual market, and to streamline the process for applying for such adjustments to reduce burdens for States and HHS.

a. Standard for Adjustment to the Medical Loss Ratio (§ 158.301)

For the reasons described above, we proposed to amend § 158.301 to permit the Secretary to adjust the individual market MLR standard in any State if the Secretary determines that there is a reasonable likelihood that an adjustment to the 80 percent MLR standard will help stabilize the individual market in that State. We are finalizing the amendments as proposed.

b. Information Regarding the State's Individual Health Insurance Market (§ 158.321)

We proposed to amend § 158.321 to modify the information that a State must submit to the Secretary with its request for an adjustment to the 80 percent MLR standard in its individual market. Specifically, because we sought to make the MLR adjustment process less burdensome on States and make adjustments available to enable States to develop innovative solutions for stabilizing their individual markets, we proposed to remove the requirements that the State must describe the State MLR standard and formula for assessing compliance (§ 158.321(a)), its market withdrawal requirements (§ 158.321(b)), and the mechanisms available to the State to provide consumers with options for alternate coverage (§ 158.321(c)). Additionally, we proposed to redesignate paragraph (d) as paragraph (a) and to revise the redesignated paragraph to describe the information the State must submit regarding the State's individual health insurance market, as outlined below.

We also proposed to replace the requirement previously codified at § 158.321(d)(1) that a State provide detailed product-level enrollment and premium data with a requirement at § 158.321(a)(2) to submit information only on the total number of enrollees (life-years and covered lives) for each type of coverage sold or renewed in the State's individual market. Similarly, we proposed to eliminate the requirement previously codified in § 158.321(d)(1) to submit product-level premium data in favor of the total earned premium data in the proposed § 158.321(a)(1), and to eliminate the § 158.321(d)(1) requirement to submit the issuer's individual market share.

We proposed to continue to require States to include information on total earned premium (proposed § 158.321(a)(1)) and total agent and broker commission expenses (proposed § 158.321(a)(3)) for each type of coverage sold or renewed in the State's individual market, as described in more detail below, as well as the risk-based capital (RBC) level (proposed § 158.321(a)(5)), which, due to the manner in which RBC is calculated, would only be appropriate to report at the issuer level, rather than for each type of coverage. We also proposed to revise the accompanying regulation text for these data elements for readability. We further proposed that State requests should include information on total incurred claims (proposed § 158.321(a)(1)) for each type of individual market coverage described below, in lieu of the previous more burdensome requirement to provide reported and estimated individual market MLRs (§ 158.321(d)(2)(ii) through (iii)).

We proposed to modify these requirements to require States to only include the information for each issuer actively offering individual market coverage. We also proposed to add a new § 158.321(b) to require that a State request include the individual market data required in the proposed new § 158.321(a)(1) through (4) and (6) separately for each issuer actively offering individual market plans in that State group by the following categories, as applicable: On-Exchange, off-Exchange, grandfathered health plans as defined in § 147.140, coverage that meets the criteria for transitional policies outlined in applicable guidance,[99] and non-grandfathered single risk pool coverage, in order to enable the Secretary to assess the situation in the State's individual market and to appropriately evaluate the State's proposal. Proposed new § 158.321(b) would also require the State to report the RBC information at the issuer level for each issuer actively offering coverage in the State's individual market. A State would not be required to provide information on student health insurance coverage as defined in § 147.145 or individual market excepted benefits as defined in § 148.220.

To further reduce the burden on States, we proposed to remove the requirements to provide net underwriting profit for each issuer's total business in the State and after-tax profit and profit margin for the individual market and total business in the State (§ 158.321(d)(2)(vii)), as well as to rename the remaining requirement to provide the individual market ''net underwriting profit'' to ''net underwriting gain'' to more accurately reflect the accounting term (proposed § 158.321(a)(4)). We also proposed to delete the requirement to provide information on estimated MLR rebates (§ 158.321(d)(2)(v)). Additionally, we proposed to revise the language at current paragraph § 158.321(d)(2)(ix), proposed to be redesignated at § 158.321(a)(6), to require the State to provide information not only on notices by issuers covered in § 158.321(a) of market exits, but also the equally or more pertinent issuer notices of beginning to offer coverage in the individual market, as well as ceasing or commencing offering individual market coverage on the Exchange or in specific geographic areas (for example, counties); and to add a new § 158.321(c) to require similar information on issuers not actively offering coverage in the individual market that have indicated an intent to enter or exit the individual market, including ceasing or commencing offering individual market coverage on the Exchange or in specific geographic areas. Lastly, we recognize that in many situations the information proposed to be required in § 158.321(a) will only be available for the preceding calendar year, but we proposed to provide States with an option to also include information for the current year (where available), which may be more

[99] See, for example, CMS ''Insurance Standards Bulletin Series—Information—Extension of Transitional Policy through Calendar Year 2018 (February 23, 2017) available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Extension-Transitional-Policy-CY2018.pdf*.

relevant if a State makes a request in a later part of the year.

We are finalizing the amendments as proposed, with one correction to § 158.321(b) to indicate that the information required in paragraph § 158.321(a)(5) is the only information that must be provided at the issuer level.

c. Proposal for Adjusted Medical Loss Ratio (§ 158.322)

To reduce the burden on States, we proposed to remove paragraphs (a), (c) and (d) of § 158.322, which would remove the requirements for a State to justify how its proposed adjustment was determined, and to estimate rebates that would be paid with and without an adjustment because HHS can make these estimates instead of the State. Consistent with our proposed changes to § 158.301, we proposed to revise § 158.322 to require the State to both provide its proposed, adjusted MLR standard and explain how this proposed standard would help stabilize its individual market. We also proposed to delete current paragraph (b), which requires an explanation of how an adjustment would permit issuers to adjust current business models and practices in order to meet an 80 percent MLR as soon as is practicable, to further reduce burden on States submitting adjustment requests.

We are finalizing the amendments as proposed.

d. Criteria for Assessing Request for Adjustment to the Medical Loss Ratio (§ 158.330)

Section 158.330 lists the criteria that the Secretary may consider in determining whether to approve a State request to adjust the 80 percent MLR standard for the individual market. We proposed amendments throughout the section to reflect the proposal in § 158.301 to allow adjustments if the Secretary determines the adjustment would help stabilize the individual market in that State, and the proposed changes to the information requirements in § 158.321. Specifically, we proposed conforming amendments to the introductory text of § 158.330 to provide that the Secretary may consider the identified criteria when assessing whether an adjustment to the individual market MLR standard would be reasonably likely to help stabilize the individual market in a State that has requested such an adjustment. We proposed to replace the information currently outlined at § 158.330(a)(1)–(4) regarding individual market issuers reasonably likely to exit the State with information regarding the number and financial performance of issuers actively offering individual market coverage on-Exchange, off-Exchange, grandfathered health plans as defined in § 147.140, coverage that meets the criteria for transitional policies outlined in applicable guidance, and non-grandfathered single risk pool coverage; the number of issuers reasonably likely to cease or begin offering such individual market coverage in the State; and the likelihood that an adjustment would increase competition in the State's individual market, including in underserved areas (proposed § 158.330(a)). We proposed to delete the existing criteria captured at § 158.330(b) related to consideration of the number of individual market enrollees covered by issuers that are reasonably likely to exit the State's individual market absent the requested adjustment because the goal of a State request for adjustment may be to ensure that health insurance coverage is available to all, rather than a certain percentage of, consumers who want it, and that consumers not only have coverage, but also a choice of several issuers. We proposed conforming amendments to the criteria currently captured at § 158.330(c), proposed to be redesignated at § 158.330(b), regarding whether an adjustment might improve consumers' access to agents and brokers. Similar to the proposed amendments to § 158.321 described above to remove the requirement for States to provide information on available mechanisms to provide alternate coverage, we proposed to replace the current criteria outlined at § 158.330(d)(1)–(5) with consideration of information on the capacity of any new issuers or issuers remaining in the individual market to write additional business in the event one or more issuers were to cease or begin offering individual market coverage on Exchanges, in certain geographic areas, or in the entire individual market in the State (proposed § 158.330(c)). We proposed to retain and modify the existing criteria at § 158.330(e), proposed to be redesignated at § 158.330(d), on the impact on premiums charged, and on benefits and cost sharing provided, to consumers by issuers remaining in or entering the individual market in the event one or more issuers were to cease offering individual market coverage on the Exchange, in certain geographic areas, or in the entire individual market in the State. Finally, we proposed to retain the existing criteria at § 158.330(f), proposed to be redesignated at § 158.330(e), for consideration of any other relevant information submitted by the State.

We are finalizing the amendments as proposed.

e. Treatment as a Public Document (§ 158.341)

Because the format in which States may submit requests for adjustments may not comply with Federal requirements for documents posted on Federal websites, some of these documents may not be able to be posted directly to the applicable Federal website. For example, a State may submit spreadsheets containing data or copies of issuer letters in a format that is not accessible for individuals with visual impairments. However, HHS is committed to transparency and making this information promptly available to the public. HHS is also committed to providing accessible information to members of the public, including individuals with disabilities, and will provide such individuals with accessible copies of documents submitted by States unless doing so would impose an undue burden on the agency. Therefore, we proposed to amend § 158.341 to reflect that Federal requirements for documents posted on Federal websites may not permit these documents to be posted, and to specify that instructions for the public to access information on requests for adjustment to the MLR standard submitted by States will be provided on the Secretary's internet website. We are finalizing the amendments as proposed, with a non-substantive change to the regulatory text.

f. Subsequent Requests for Adjustment to the Medical Loss Ratio (§ 158.350)

We proposed to make conforming amendments to § 158.350, which describes the information that a State must submit with a subsequent request for an adjustment to the MLR standard, to make this information consistent with our proposed changes to § 158.301 and § 158.330. We are finalizing the amendments as proposed.

The following is a summary of the public comments received on these proposals and our responses.

Comment: We received comments from consumer and patient advocacy groups, health insurance issuers, States, and individuals regarding the proposal to modify the process for submission of State requests to adjust the individual market MLR standard and the accompanying criteria for the Secretary to determine whether to adjust the 80 percent MLR standard in the individual market in a State. The majority of comments focused on the merits of the

proposed amendments to subpart C as a whole, rather than offering comments on the specific sections of subpart C. Most commenters opposing the proposals stated that it is unlikely that the MLR standard is a primary driver of market instability and that most insurers already meet or exceed the MLR standard. These commenters stated that lowering the MLR standard would undermine one of the few consumer protections and lead to higher premiums with consumers receiving lower value for those premiums, without strengthening the market. Many commenters focused on the benefits the MLR rule has delivered to consumers and objected to weakening the rule. Several commenters expressed concern that the proposal could lead to discrepancies in standards and access to care. Several commenters disagreed with the proposed elimination or reduction of various requirements on States seeking adjustments due to concerns over the possibility of arbitrary and unjustified requests, inadequately rigorous review, and a decrease in transparency. Most commenters who supported the proposals expressed appreciation that the proposals would give greater flexibility to the States. Some of these commenters stated that a lower MLR standard may have competitive benefits that outweigh potential costs and that States are in the best position to assess that tradeoff. Several commenters stated that the proposals could incentivize issuer expansion and innovation. Additionally, several commenters recommended that States be allowed to only lower (not increase) the MLR standard, and that adjustments not be effective prior to 2020 in order to give issuers time to incorporate adjusted MLR standards into issuers' market participation and pricing decisions. Lastly, one commenter recommended allowing States to adjust the MLR standard for only specific issuers, such as new entrants, while another commenter urged HHS to disallow this in order to not disadvantage established issuers and to avoid encouraging such issuers to leave the market.

Response: We are finalizing the proposed amendments to subpart C as proposed, with one technical correction to § 158.321(b) to indicate that the information required in paragraph § 158.321(a)(5) is the only section that must be provided at the issuer level. We appreciate both the comments highlighting the benefits of the current MLR rule, as well as the comments supporting our efforts to provide more flexibility to States to improve the stability of their markets. We acknowledge the concerns expressed by many commenters that the adjustments to the individual market MLR standard should not undermine consumer protections and that the integrity of the adjustment review process should not be compromised. However, we believe that if States can develop strategies involving an adjusted MLR standard that States can demonstrate would be reasonably likely to lead to a more robust and stable individual market, then this would benefit consumers and ultimately lead to higher quality and more affordable coverage. We note that the amendments to subpart C are not intended to reduce the overall burden of proof on States applying for adjustments, but rather require States to provide more pertinent information and remove duplicative, burdensome requirements, such as those that mandate States submit data that is otherwise publicly available to both HHS and consumers. Given that the goal of the amendments to subpart C is to provide States the flexibility to innovate and pursue the best solutions for their markets, we believe that it would be inconsistent to impose up-front restrictions on how much or what direction of an adjustment a State may seek. For the same reason, we will determine the effective date for each adjustment in consultation with the respective State and based on the timing of the request submitted by the State, but will, as appropriate, take commenters' recommendations on the proposed rule into consideration when making those determinations. We further clarify that a State should include an effective date and duration (for up to 3 MLR reporting years [100]) for the requested adjustment to the individual market MLR standard as part of its proposal. In addition, we note there will be opportunities for public comment on individual State adjustment requests. Sections 158.342 and 158.343 are being retained in their current form, which require the Secretary to invite public comment on State adjustment requests and provide for optional State public hearings, respectively. Lastly, because we interpret the statute as only permitting the Secretary to adjust the MLR standard for the entire individual market within a State, we are not able to allow issuer-specific adjustments within a State. However, we note that there are several other provisions in the MLR regulations that are designed to recognize the special circumstances of smaller and newer plans, and provide incentives for issuers that contemplate entering a market. These include the credibility adjustment for smaller issuers in § 158.323 and the options to defer MLR and rebate calculation for newer business in § 158.121 and to limit the total rebate payment in § 158.240(d).

[100] See 45 CFR 158.311.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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. This final rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 12. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicited comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.[101] Table 11 in this final rule presents the mean hourly wage (calculated at 100 percent of salary), the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor

[101] See May 2016 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates at *https://www.bls.gov/oes/current/oes_nat.htm*. For State Government Employees see NAICS 999200—State Government, excluding schools and hospitals (OES Designation) *https://www.bls.gov/oes/current/naics4_999200.htm*.

of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 11—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES

Occupation title	Occupational code	Mean hourly wage ($/hr.)	Fringe benefits and overhead ($/hr.)	Adjusted hourly wage ($/hr.)
Business operation specialist *	13–1199	$31.59	$31.59	$63.18
Operations Manager	11–1021	58.70	58.70	117.40
Software Developers, Systems Software	15–1133	53.17	53.17	106.34
Actuary	15–2011	54.87	54.87	109.74
Actuary *	15–2011	40.41	40.41	80.82
Financial Examiner *	13–2061	33.02	33.02	66.04
Financial Analyst *	13–2051	34.39	34.39	68.78
Financial Manager *	11–3031	45.83	45.83	91.66
Lawyer *	23–1011	44.87	44.87	89.74
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43–6014	17.38	17.38	34.76
Commissioner **		58.45	58.45	116.90
Market Research Analyst	13–1161	33.95	33.95	67.90
Medical Records Technician	29–2071	19.93	19.93	39.86
Psychiatrist	29–1066	96.26	96.26	192.52

* Denotes occupations where wages were obtained for State Government employees (*https://www.bls.gov/oes/current/naics4_999200.htm*).
** Data on compensation of State Insurance Commissioners collected by the Council of State Governments and compiled by Ballotpedia (*http://www.ballotpedia.org*). The wage data used in the burden estimates include the cost of fringe benefits and the adjusted hourly wage.

B. ICRs Regarding State Flexibility for Risk Adjustment (§ 153.320)

We are finalizing our proposal to allow State regulators to request a reduction, beginning for the 2020 benefit year, to risk adjustment transfers in the individual, small group or merged markets. We are finalizing the requirement for any State requesting this reduction to otherwise applicable transfers to submit its request with the supporting evidence and analysis to HHS identifying the State-specific factors that warrant the adjustment to more precisely account for the differences in actuarial risk in the State's individual, small group or merged market. Additionally, the State must submit supporting evidence and analysis demonstrating the reduction percentage requested is appropriate. This evidence and analysis justifying the percentage requested must either demonstrate the set of factors and the percentage by which those factors warrant an adjustment to more precisely account for the differences in actuarial risk in the State's individual, small group or merged market compared to the national norm, or it must demonstrate the requested reduction in risk adjustment payments would be so small for issuers who would receive risk adjustment payments, that the reduction would have a *de minimis* effect on the necessary premium increase to cover the affected issuer or issuers' reduced payments. States are required to submit the requests with the supporting evidence and analysis by August 1st, 2 calendar years prior to the beginning of the applicable benefit year (for example, August 1, 2018, for the 2020 benefit year). The burden associated with this requirement is the time and effort for the State regulators to submit its request and supporting evidence and analysis to HHS. We are updating the burden estimates from those proposed based on the State request and supporting evidence and analysis requirements we are finalizing in this rule. We estimate submitting the request and supporting evidence and analysis will take a business operations specialist 40 hours (at a rate of $63.18 per hour) to prepare the request and 20 hours for a senior manager (at a rate of $117.40 per hour) to review the request and transmit it electronically to HHS. We estimate that each State seeking a reduction will incur a burden of 60 hours at a cost of approximately $4,875 per State to comply with this reporting requirement (40 hours for the insurance operations analyst and 20 hours for the senior manager). Although we are unable to precisely estimate the number of States that will make this request, we expect that no more than 25 States will make these requests annually, resulting in a total annual burden of approximately 1,500 hours with an associated total cost of $121,880. We published a revised information collection approved under OMB control number 0938–1155: Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals, for comment on December 28, 2017, and intend to update it to account for this change in burden.

C. ICRs Regarding Risk Adjustment Data Validation (§ 153.630)

We finalize that, beginning with 2017 benefit year risk adjustment data validation, issuers with 500 billable member months or fewer Statewide that elect to establish and submit data to an EDGE server will not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results. We note that, beginning with 2018 benefit year risk adjustment data validation, these issuers will not be subject to random sampling under the materiality threshold discussed below, and will continue to not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results. As 2016 benefit year risk adjustment data validation will be another pilot year, we are also finalizing the postponement of the application of the materiality threshold to the 2018 benefit year. Under this policy, all issuers of risk adjustment covered plans will be required to conduct an initial validation audit for the 2017 benefit year risk adjustment data validation, other than issuers with 500 billable member months or fewer Statewide as discussed above. Beginning with the 2018 benefit year, issuers below the $15 million premium materiality threshold will not be

required to conduct an initial validation audit every year, but rather, HHS will conduct random and targeted sampling under which issuers below the materiality threshold would be subject to an initial validation audit approximately every 3 years.

HHS estimates that not requiring issuers that have 500 or fewer billable member months Statewide to conduct an initial validation audit beginning in the 2017 benefit year will exempt 50 issuers from an initial validation audit and reduce administrative costs for each issuer by 828 hours with an estimated cost reduction on average of up to $100,000. The total burden reduction for all 50 issuers will be 41,400 hours with an associated reduction in cost of $3,520,000. The postponement of the effectiveness of the materiality threshold to the 2018 benefit year will not impact issuer burden relative to previous estimates for the risk adjustment data validation program included in the 2014 and 2015 Payment Notices, particularly given that the program has been converted to a pilot for the first 2 years of operation. We are revising the current information collection approved under OMB control number 0938–1155: Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals, to account for this reduction in burden.

For risk adjustment data validation, HHS requires issuers to document mental and behavioral health records included in audit sampling. Without the necessary mental and behavioral health information for each sample, the diagnosis code for an applicable enrollee cannot be validated and, therefore, it would be rejected during risk adjustment data validation.

Because providers may be prevented by some State privacy laws from furnishing a full mental health or behavioral health record, we are amending § 153.630(b)(6) to allow issuers an additional avenue to achieve compliance with data validation requirements by permitting the submission of mental or behavioral health assessments for risk adjustment data validation in the event that a provider is subject to State privacy laws that prohibit the provider from providing HHS with a complete mental or behavioral health record. For risk adjustment data validation purposes, to the extent permissible under applicable Federal and State privacy laws, an assessment should contain: (1) The enrollee's name; (2) sex; (3) date of birth; (4) current status of all mental or behavioral health diagnoses; and (5) dates of service. To submit a mental or behavioral health assessment, an issuer must ensure that it is accompanied by an attestation from the provider that applicable State privacy laws prevent him or her from providing the complete mental or behavioral health record.

HHS expects that this provision may affect 10 percent of issuers or approximately 70 issuers in States with stricter privacy laws on medical records. Based on our experience with the first pilot year risk adjustment data validation audits, we estimate that approximately 40 enrollees in any initial validation audit sample of 200 enrollees could be affected. Since providers routinely prepare mental or behavioral health assessments to validate diagnoses, we believe the slight additional burden is the time it would take to seek patient consent to provide the assessment, in States that require such permission, to review and edit the preexisting assessment for each medical record to include the data elements specified in § 153.630(b)(6), and to attest that relevant State privacy laws prohibit him or her from providing the complete mental or behavioral health record.

Comment: Several commenters stated that obtaining patient consent and provider attestations for mental or behavioral health assessments would impose a significant administrative, professional, and personal burden on issuers, providers, and patients, while one commenter stated that this flexibility could reduce administrative burden if issuers could develop a standard form for physicians to sign.

Response: As noted above, HHS believes that the policy to permit the use of existing mental or behavioral health assessments may result in a slight increase in the burden on issuers and providers, primarily due to the new provider attestation requirement.

We estimate it will take a medical records technician (at an hourly rate of $39.86) 15 minutes to obtain consent from each patient, or approximately 10 burden hours at an estimated cost of $399 per issuer. In addition, we estimate a qualified licensed provider (psychiatrist, at an hourly rate of $192.52) will need 45 minutes to prepare an abbreviated assessment and sign an attestation, for a total of $144 per enrollee, or $5,776 per issuer. Therefore, for 40 patients, the total burden per issuer for the provider to obtain consent from each patient and prepare an abbreviated assessment and signed attestation will be 40 hours and approximately $6,174. The aggregated burden for the estimated 70 affected issuers will be 2,800 hours and approximately $432,194. We are revising the current information collection approved under OMB Control Number 0938–1155: Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals, to account for this additional burden.

D. ICRs Regarding Health Insurance Issuer Rate Increases: Disclosure and Review Requirements—Applicability (§ 154.103)

We are finalizing the proposal to exempt student health insurance coverage as defined in § 147.145 from the Federal rate review requirements. Because we will no longer be reviewing the reasonableness of rate increases for student health insurance coverage, we expect to collect less information for the 2019 plan or policy year than collected for previous years. This will reduce burden related to the submission and review for issuers and States. We estimate that 75 student health insurance issuers will no longer be required to submit rate increases to HHS. We estimate that each rate review submission takes 11 hours for an actuary (at a rate of $109.74 per hour) to prepare, and that each issuer will submit an average of 2.5 plans, at an estimated annual cost of $3,018, resulting in a total reduction in the annual burden to issuers of approximately 2,063 hours and an associated reduction in cost of approximately $226,339. We estimate that States will no longer submit rate increases for 188 student health insurance plans to HHS. We estimate a reduction in burden to States of one hour per plan for an actuary (at a rate of $80.82 per hour) to prepare and electronically submit the appropriate materials, for a total reduction in burden of approximately 188 hours annually with an associated cost reduction of approximately $15,194. We will revise our current burden estimate approved under OMB control number 0938–1141: Rate Increase Disclosure and Review Reporting Requirements, to reflect the reduced burden on States and issuers.

E. ICRs Regarding Rate Increases Subject To Review (§ 154.200)

We are finalizing our proposal to establish a 15 percent Federal default threshold for reasonableness review. We expect this to reduce burden for issuers because Part II of the Rate Filing Justification (Consumer Justification Narrative) is only required for increases that meet or exceed the threshold. In the 2019 plan year, we estimate that the number of written justifications that will be submitted will decrease by approximately 125 submissions. That estimate is based on data from the 2018 plan year. We reached this estimate by counting the number of submissions

with a product subject to review due to an increase between 10 percent and 15 percent. Specifically, CMS received 786 submissions for the 2018 plan year; 579 of those included a rate increase at or above 10 percent; while 454 of those included a rate increase at or above 15 percent, resulting in 125 submissions falling between 10 percent and 15 percent.

We estimate that each written justification will require 1.5 hours for an actuary (at a cost of $109.74 per hour) to prepare and electronically transmit the documentation. Therefore, the annual burden for issuers will be reduced by 187.5 hours, with an estimated annual savings of $20,576.

As stated above, we estimate 125 fewer submissions with rate increases subject to review. Assuming that States adopt the Federal default threshold, we expect the number of State reviews will decrease by 123 submissions.[102] We estimate that each State review will require 38.5 hours of work by an actuary (at a cost of $80.82 per hour). Therefore, the State burden will decrease by approximately 4,735.5 hours, with an estimated annual savings of $382,723.

We will revise our current burden estimate approved under OMB control number 0938–1141: Rate Increase Disclosure and Review Reporting Requirements, to reflect the reduced burden on issuers.

F. ICRs Regarding the Small Business Health Options Program (SHOP)

We are finalizing the proposals granting additional flexibilities, effective on the effective date of this rule and applicable for plan years beginning on or after January 1, 2018, to SHOPs, to qualified employers and employees enrolling in SHOP plans, and to participating QHP issuers and SHOP-registered agents and brokers in how they interact with a SHOP. Under the proposals being finalized throughout this document, SHOPs will no longer be required to provide enrollment, premium aggregation functions, and online enrollment functionality through a SHOP website, and the FF–SHOPs and SBE–FPs for SHOP, will no longer continue to perform these functions. Instead, small groups will enroll in a SHOP plan through a SHOP-registered agent or broker or through a participating QHP issuer participating in a SHOP. FF–SHOPs will follow the approach as outlined in this final rule. SBEs will have the flexibility to operate their SHOP in a way that meets the needs of their State and complies with the regulatory flexibilities outlined herein.

Under the proposals being finalized in this rule several pieces of information currently being collected by a SHOP may no longer be collected by a SHOP, or, the way in which the information is collected may change. For example, employers, employees, and agents and brokers may be required to provide the information currently collected by a SHOP to an issuer for the purposes of enrollment in a SHOP plan. A SHOP, like the FF–SHOPs and SBE–FPs for SHOP, however, will not be the entity collecting the information and the Federal government thus will experience a reduction in burden. Under the new regulatory flexibilities being finalized and described throughout this rule, employers and employees will no longer be required to visit a SHOP website in order to enroll in a SHOP plan and a SHOP will no longer be required to have the capability or the need to collect enrollment information. Employers will however, be required to apply to the SHOP to obtain an eligibility determination, as described in § 155.710, at which point the employer will be requested to provide: (1) Employer name and address of employer's locations; (2) Information sufficient to confirm the employer is a small employer; (3) Employer Identification Number (EIN); and (4) Information sufficient to confirm that the employer is offering, at a minimum, all full-time employees coverage in a QHP through a SHOP. Under current regulations, the employer provides, and a SHOP collects, this information as part of enrolling in a SHOP QHP through a SHOP. HHS previously estimated that an employer needed two hours to complete the eligibility determination when it was included as part of enrolling in a SHOP QHP and that 6,000 employers will complete an application annually to determine their eligibility through a SHOP website. Based on these criteria, HHS estimated that the total annual burden for 6,000 employers was 12,000 hours, with a total annual cost of $561,240 to complete the SHOP application and eligibility determination process. With the new regulatory flexibilities being granted to SHOPs, HHS estimates that for each employer, an administrative assistant will need less than 5 minutes (at rate of $34.76 per hour) to complete the required eligibility determination. Under the new flexibilities, employers will also no longer be required to create an account on an FF–SHOP website in order to complete the eligibility determination or enroll in a SHOP QHP. Therefore, HHS estimates that it will cost an employer approximately $3 to complete an eligibility determination. Assuming that 6,000 employers will complete an eligibility determination, HHS estimates that the total annual burden will be approximately 500 hours, with an estimated total cost of $17,400. This will result in a net burden reduction of 11,500 hours and a net cost reduction of approximately $543,840 annually. Under § 157.206(e)(1), employers will be responsible for submitting a new eligibility determination or, submitting a notice of withdrawal, in the event the group experienced a change that will impact the group's eligibility to participate in a SHOP. Under § 157.206(e)(2), employers will also be required to notify their QHP issuer(s) of a determination of ineligibility. Finally, employers will also, under § 157.206(e)(3) be required to notify their issuers of their intent to no longer participate in a SHOP. While these proposals will require employers to communicate with issuers in ways they do not under current SHOP enrollment practices, HHS does not anticipate that these practices will increase the burden on employers as they, under current practice, must notify the SHOP of changes in eligibility and termination. Although the policy in § 155.716 imposes an information collection requirement, the information that will be collected is no different from what is already approved under OMB control number 0938–1193: Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses in the Small Business Health Options, and therefore we are not revising the information collection at this time.

Employees, under § 155.716 will not experience an increase in burden. Under the policies described throughout this final rule, employees will no longer be required to visit an FF–SHOP website to create an account, or, for any application or enrollment purpose, but they may need to provide similar information to an agent or broker or issuer as a condition of enrollment into a SHOP QHP. HHS previously estimated that 60,000 employees will complete an application annually, each spending approximately one hour to complete an online application through an FF–SHOP website. The estimated annual burden was 60,000 hours with an annual cost of $1,025,400. With the finalized flexibilities to a SHOP as described in this rule, HHS predicts that the burden on employees to complete an online application will shift as no application

[102] For the 2018 plan year, CMS reviewed two submissions proposing a rate increase between 10 percent and 15 percent.

will be provided through a SHOP website, but the information may be required by an agent or broker or an issuer in order for the employee to complete an enrollment into a SHOP QHP. The proposals described throughout this final rule will allow agents and brokers and issuers to enroll consumers in SHOP plans using the channels they are most familiar with, potentially reducing the burden of enrolling SHOP groups. This information collection is currently approved under OMB control number 0938–1194: Data Collection to Support Eligibility Determinations and Enrollment for Employees in the Small Business Health Options Program. Therefore, we are not revising the information collection at this time.

Sections 155.705, 155.715, 155.720, 155.725, require SHOPs to generate certain notices. These notices may include: (1) Notices of annual election periods; (2) notices to employers of employee coverage terminations; (3) notices of application inconsistencies; (4) notices of appeal rights and instructions; (5) notices of employee and employer eligibility; (6) notices of employer withdrawal; (7) (in FF–SHOPs only) notices to employees if a dependent turns 26 and is no longer eligible for dependent coverage; (8) billing invoices, successful and unsuccessful payment confirmation notices; and (9) past due payment notices. In prior guidance, HHS previously estimated costs for paper notices in an FF–SHOP. In that estimate, HHS assumed that 80 percent of enrollees requested electronic notices and 20 percent of enrollees requested paper notices. HHS estimated that mailing paper notices costs a SHOP Exchange $0.53 per notice. HHS determined that SHOPs sent approximately 48,000 notices to enrollees when—(1) A dependent became ineligible to remain on the plan; (2) successful payment was processed; and (3) a payment was unsuccessful in the last year. Assuming that 20 percent of enrollees will opt to receive paper notices instead of electronic notifications, HHS estimated that approximately 9,600 notices will be sent, costing FF–SHOPs approximately $5,088. Under the flexibilities being finalized, SHOPs will only be required to send notices of employer eligibility and appeals. This cost will not directly be transferred to issuers as issuers may already be required to send such notices per other applicable State and Federal law. This collection is currently approved under OMB control number 0938–1207: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment. Issuers will be required to collect premiums, as premium aggregation functions will no longer be provided by the SHOPs that take advantage of the new flexibilities. HHS does not anticipate a significant increase of issuers' burden in this scenario, as it is not significantly different from their current operating practices.

G. ICRs Regarding Essential Health Benefits (§ 156.111(e))

In the rule, we are finalizing at § 156.111(e) to revise the collection of data for selection of States' EHB-benchmark plans for plan years beginning on or after January 1, 2020. This proposal includes the documentation that States would be required to submit if the State chooses to change its EHB-benchmark plan. For this purpose, we are amending the currently approved information collection (OMB Control Number: 0938–1174) to reflect the finalized policy in this rule. Because § 156.111(e) is replacing the current data collection requirements at § 156.120, we are updating the current EHB-benchmark plan selection to account for the new regulation and any associated burden with this requirement that falls on those States that choose to reselect their EHB-benchmark plan. Under the previous benchmark plan selection policy, 29 States selected one of the 10 base-benchmark plan options and 22 States defaulted. The previous benchmark plan policy did not allow for States to make an annual selection. The regulation allows States the opportunity to modify their EHB-benchmark plans annually. The regulation also does not require the State to respond to this ICR for any year for which they did not change their EHB-benchmark plan. As such, for purposes of the new EHB-benchmark plan selection options finalized in this rule, we estimate that 10 States would choose to make a change to their EHB-benchmark plans in any given year (total of 30 States over 3 years within the authorization of this ICR) and respond to this ICR.

To select a new EHB-benchmark plan, we require at § 156.111(e)(1) that the State provide confirmation that the State's EHB-benchmark plan selection complies with certain requirements, including those under § 156.111(a), (b), and (c). To complete this requirement, we estimate that a financial examiner will require 4 hours (at a rate of $66.04 per hour) to fill out, review, and transmit a complete and accurate document. We estimate that it costs each State $264 to meet this reporting requirement, with a total annual burden for all 10 States of 40 hours and an associated total cost of $2,642.

Second, we require at § 156.111(e)(2) that the State submit an actuarial certification and associated actuarial report of the methods and assumptions when selecting options under § 156.111(a). Specifically, we are finalizing at § 156.111(b)(2)(i) and (ii) that a State's EHB- benchmark plan must provide a scope of benefits equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, and that the State's EHB-benchmark plan must not exceed the generosity of the most generous among a set of comparison plans. The actuarial certification that is being collected under this ICR is required to include an actuarial report that complies with generally accepted actuarial principles and methodologies. This estimate includes complying with all applicable ASOPs. For example, ASOP 41 on actuarial communications includes disclosure requirements, including those that apply to the disclosure of information on the methods and assumptions being used and ASOP 50 contains information on determining MV and AV. In accordance with ASOP 41, we would expect that the actuarial report is based on a data analysis that is reflective of an appropriate population. The actuarial certification for this requirement is provided in a template and includes an attestation that the standard actuarial practices have been followed or that exceptions have been noted. The signing actuary is required to be a Member of the American Academy of Actuaries.

We estimate that an actuary, who is a member of the American Academy of Actuaries, requires 18 hours (at a rate of $80.82 per hour) on average for § 156.111(e)(2). This includes the certification and associated actuarial report from an actuary to affirm, in accordance with generally accepted actuarial principles and methodologies, that the State's EHB-benchmark plan provides a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within an EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, and that the State's EHB-benchmark plan definition does not exceed the generosity of the most generous among the set of comparison plans. We are also finalizing a document entitled *Example*

of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with 45 CFR 156.111(b)(2)(i) and (ii)[103] that provides an example of a method an actuary could use to develop the actuarial certification and associated report at § 156.111(e)(2) for both the typical employer plan and comparison plan standards.

For these calculations, the actuary needs to conduct the appropriate calculations to create and review an actuarial certification and associated actuarial report, including minimal time required for recordkeeping. The precise level of effort for the actuarial certification and associated actuarial report under § 156.111(e)(2) will likely vary depending on the State's approach to its EHB-benchmark plan and this certification requirement. For example, as described in the *Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with 45 CFR 156.111(b)(2)(i) and (ii),* to reduce the burden of these standards, the actuary may want to consider using the same plan for both the generosity and the typicality tests, provided that the plan meets the standards at both § 156.111(b)(2)(i) and (ii). For example, the actuary may only need to do one plan comparison for the purposes of both of these certification requirements. Specifically, the actuary could use the same plan, such as the State's EHB-benchmark plan used for the 2017 plan year. That plan would, by definition, be a ''Comparison Plan.'' Because the State's EHB-benchmark plan used for the 2017 plan year would simply be one of the State's base-benchmark plans, supplemented as necessary under § 156.110, that plan also could be used for purposes of determining typicality, as a proposed State EHB-benchmark plan that was equal in scope of benefits to the State's EHB-benchmark plan used for the 2017 plan year within each EHB category at § 156.110(a) would be equal to or greater in scope of benefits within each EHB category at § 156.110(a) than the base-benchmark plan underlying the EHB-benchmark plan used for the 2017 plan year, to the extent of the required supplementation. We estimate that a financial examiner will require 1 hour (at a rate of $66.04 per hour) to review, combine, and electronically transmit these documents to HHS, as part of a State's EHB-benchmark plan submission.

We increased the estimated burden hours from 16 hours to 18 hours for the actuary to complete the actuarial certification and associated report in recognition of the extension of the generosity standard and in recognition that the definition of typical employer plan may require the actuary to determine whether the typical employer plan meets MV requirements. We are also increasing the estimated number of States that need to respond to this section of the ICR from 7 to 10 since the typical employer plan standard and the generosity standard applies to all State's EHB-benchmark plan options at § 156.111(a). We estimate that each State incurs a burden of 19 hours with an associated cost of $1,520.80 with a total annual burden for 10 States of 190 hours at associated total cost of $15,208. We did not receive comments on this specific estimate.

Third, we require at § 156.111(e)(3) each State to submit its proposed EHB-benchmark plan documents. The level of effort associated with this requirement will depend on the State's selection of the EHB-benchmark plan options under the regulation at § 156.111(a). However, for the purposes of this estimate, we estimate that it requires a financial examiner (at a rate of $66.04 per hour) 12 hours on average to create, review, and electronically transmit the State's EHB-benchmark plan document that accurately reflects the benefits and limitations, including medical management requirements and a schedule of benefits, resulting in a burden of 12 hours and an associated cost of $792, with a total annual burden for all 10 States of 120 hours and an associated cost of $7,925. The burden for producing these documents is significantly higher than previous estimates because the previous data collection generally only required the State (or issuer) to transmit the selected benchmark plan document. In contrast, in some cases, the § 156.111(a) may result in the State needing to create a completely new document or significantly modify the current document to represent the plan document. Additionally, this estimate of 12 hours also includes the burden necessary for a State selecting the option at § 156.111(e)(3) where the State is required to submit a formulary drug list for the State's EHB-benchmark plan in a format and manner specified by HHS. Specifically, the burden for the State selecting this option is also likely to vary as the State could use an existing formulary drug list or create its own formulary drug list separately for this purpose. To collect the formulary drug list, the State is required to use the template provided by HHS and submit the formulary drug list as a list of RxNorm Concept Unique Identifiers (RxCUIs).

Section 156.111(e)(4) requires the State to submit the documentation necessary to operationalize the State's EHB-benchmark plan. This reporting requirement includes the EHB summary file that is currently posted on CCIIO's website, used as part of the QHP certification process, and integrated into HHS's IT Build systems that feed into the data that is displayed on *HealthCare.gov*. While this document is not a new document, the burden associated with this document is new for States. We estimate that it requires a financial examiner 12 hours, on average, (at a rate of $66.04 per hour) to create, review, and electronically submit a complete and accurate document to HHS resulting in a burden of 12 hours and an associated cost of $792, with a total annual burden for all 10 States of 120 hours and an associated cost of $7,925.

Under the previous policy, the burden estimates 226 respondents per year, for a total yearly burden total of 165 annual burden hours and a total annual associated cost of $8,094 to meet these reporting requirements. Under the new policy related to EHB, we estimate that the total number of respondents will be 10 per year, for a total yearly burden of 470 hours and an associated cost of $33,699 to meet these reporting requirements. The estimated burden associated with the changes represents an increase of 305 hours (increase from 165 hours to 470 hours) and an annual costs increase of $25,605 (from $8,094 to $33,699) over the previously approved information collection (OMB Control Number: 0938–1174).

As part of the update to this OMB control number: 0938–1174, we also sought comment on requirements for SADPs to submit voluntary reporting. This collection includes data on whether the issuer intends to offer SADP coverage, the anticipated Exchange market in which coverage will be offered, and the State and service area in which the issuer offers coverage. The burden associated with meeting this requirement includes the time and effort needed by the issuer to report on whether it intends to offer SADP coverage. We estimate that it will take one half hour for a health insurance issuer to meet this reporting requirement. We estimate that approximately 175 issuers will respond to this data collection. Therefore, we anticipate that the reporting

[103] *Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with 45 CFR 156.111(b)(2)(i) and (ii) is* available at *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.html.*

requirement will require a market research analyst one half-hour annually to identify and submit the responsive records to HHS (at a rate of $67.90 per hour), for a total cost of $34 a year per reporting entity. This will result in an annual burden of 87.5 hours for all 175 issuers and a resulting estimated annual cost of $5,941. OMB approvals are issued for 3 years; therefore, the aggregate burden for 3 years will be approximately 263 hours with an associated cost of approximately $17,824. We did not receive comments on these estimates.

Lastly, as part of the update to this OMB control number: 0938–1174, we are adding an information collection request to this ICR to account for the finalized policy at § 156.115(b)(2)(ii) that allows the State the option to notify HHS that the State will allow substitution between EHB categories of benefits, beginning with the 2020 plan year. Specifically, § 156.115(b)(2)(ii) will allow issuers to substitute benefits only when the State in which the plan will be offered permits such substitution and notifies HHS of its decision to allow substitution between categories. We anticipate that States will notify HHS through the same means the States will notify HHS of an updated EHB-benchmark plan selection under § 156.111 and we intend to provide a preformatted response for States to use to provide the notification to HHS. To provide notification under § 156.115(b)(2)(ii), we estimate that it will require a financial examiner ½ hour, on average, (at a rate of $66.04 per hour) to review and electronically submit a notification to HHS. Furthermore, we estimate that at most 5 States will want to allow the flexibility for their issuers to substitute between categories under § 156.115(b)(2)(ii). While this aspect of the ICR is not subject to the PRA because we estimate that no more than 5 States will be affected annually, we nonetheless provide a total annual burden estimate for § 156.115(b)(2)(ii), which is 2.5 hours and a total associated cost of $165.

H. ICRs Regarding Medical Loss Ratio (§§ 158.170, 158.221, 158.320–323, 158.340, 158.346, and 158.350)

We are amending § 158.221 to allow issuers the option to report quality improvement activity expenses as a single fixed percentage of premium amount beginning with the 2017 MLR reporting year (that is, for reports filed by July 31, 2018), and making conforming amendments to § 158.170. We do not anticipate that implementing this provision will require significant changes to the MLR annual reporting form and the associated burden. In addition, while we are not making changes to § 158.162, pursuant to public comments, we intend to make a change to the MLR annual reporting form in order to collect the information on issuers' employment taxes separately from other taxes. We do not anticipate that implementing this provision will significantly change the reporting burden either, as issuers already include this information on the reporting form, and would simply have to include it on a different line on the form. The burden related to this collection is currently approved under OMB control number 0938–1164; Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements.

We are also amending subpart C to modify the data and narratives which a State must submit as part of the State's request for an adjustment to the MLR standard in the individual market for that State. There is no standardized application form associated with a State's request, but each request must contain certain data elements in order to receive consideration by the Secretary, which are described in §§ 158.320–158.323, 158.340, 158.346, and 158.350. The burden related to the proposed requirements was previously approved under OMB control number 0938–1114, Medical Loss Ratio (IFR) Information Collection Requirements and Supporting Regulations; the approval expired in 2014. We intend to reinstate this information collection, with modifications to reflect our finalized revisions to subpart C of part 158. The proposed rule (82 FR 51052), published on November 2, 2017, served as the 60-day notice to afford the public an opportunity to comment on this collection of information requirement.

We are eliminating collection of the following information from a State requesting an adjustment: The State MLR standard and formula for assessing compliance (§ 158.321(a)), its market withdrawal requirements (§ 158.321(b)), and the mechanisms available to the State to provide consumers with options for alternate coverage (§ 158.321(c)); as well as the net underwriting profit for the total business in the State and the after-tax profit and profit margin for the individual market and total business in the State (§ 158.321(d)(2)(vii)), and the estimated rebate (§ 158.321(d)(2)(v)) of each issuer with at least 1,000 enrollees in the State. We expect these amendments to reduce the burden on States seeking an adjustment. We are also replacing the requirement that a State requesting an adjustment must submit enrollment and premium data for every individual market issuer at the product level (§ 158.321(d)(1)) and the reported and estimated MLRs (§ 158.321(d)(2)(ii) and (iii)) for issuers with at least 1,000 enrollees, with total enrollment (life-years and covered lives), premium, and total incurred claims for only active individual market issuers, separately for five types of individual market coverage: On-Exchange plans, off-Exchange plans, grandfathered health plans as defined in § 147.140, coverage that meets the criteria for transitional policies outlined in applicable guidance, and non-grandfathered single risk pool coverage. States will not be required to provide information on student health insurance coverage as defined in § 147.145 or excepted benefits as defined in § 148.220. We expect these amendments to result in a net reduction in burden on States seeking an adjustment. We will continue to collect data on total agents' and broker's commission expenses and net underwriting gain (proposed to be redesignated from § 158.321(d)(2)(iv) and (vi) to § 158.321(a)(3) and (4), respectively) for only active individual market issuers, but separately for the five types of coverage described above. We will also continue to collect information on risk-based capital levels (proposed to be redesignated from § 158.321(d)(2)(viii) to § 158.321(a)(5)) at the issuer level. While the amendments will require more breakdown of the data than § 158.321 previously required, in most States there are more issuers with at least 1,000 enrollees than there are active issuers in the individual market, and consequently we expect that these amendments will have no net impact on the burden. Additionally, we are updating § 158.321(d)(2)(ix) to collect more specific information on issuer notices to the State of changes to participation in the State's individual market, rather than focusing exclusively on notices to exit the individual market. We do not expect this amendment to have an appreciable impact on the burden. We are further eliminating the requirement that a State requesting an adjustment provide information explaining and justifying how its proposed adjustment was determined and estimating rebates that would be paid with and without an adjustment (§ 158.322(a), (c), and (d)); as well as replacing what information a State must provide pursuant to § 158.322(b) with a requirement to explain how the adjustment would help stabilize the State's individual market. We expect these amendments to reduce the burden. Lastly, we have updated what information a State must submit with a

subsequent request for adjustment pursuant to § 158.350. We do not expect this amendment to change the burden.

Based on preliminary data analysis and previous State requests for adjustments, we estimate that approximately 22 States will submit applications in the first year. We estimate that it will take approximately 140 hours on average for each State to complete the application, including gathering and analyzing data, synthesizing information, and developing a proposal for an adjusted MLR standard. Specifically, we assume that the application will take a financial analyst approximately 96 hours (at a rate of $68.78 per hour), an actuary 6 hours (at a rate of $80.82 per hour), a financial manager 10 hours (at a rate of $91.66 per hour), a lawyer 24 hours (at a rate of $89.74 per hour), and the insurance commissioner 4 hours (at a rate of $116.90 per hour) to assemble and review the various components of the application, resulting in a total burden for each State of 140 hours with an associated cost of $10,626 per response, representing an estimated total burden reduction of 45 hours per response. The documents will be submitted electronically at minimal cost. We estimate that the total burden for 22 States to submit a request for an adjustment to the individual market MLR standard will be 3,080 hours with an associated cost of approximately $233,767, with an estimated net total reduction in burden of 620 hours. We recognize that this burden may vary between States, as some States may have better access to the required application information elements, while other States may have to seek some of the required information from health insurance issuers in their States, which could increase their burden. Some States may, if providing the requested information is an undue burden, ask the Secretary to consider their application without some of the information elements. We received a few comments that generally questioned whether the burden on States related to the information collection requirements prior to the finalized amendments may have been overstated, but that did not specify the basis for such concerns and did not relate to the estimates for the revised information collection requirements. We also received one comment that agreed with the estimates for the revised information collection.

I. Summary of Annual Burden Estimates for Final Requirements

TABLE 12—FINAL ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)	Total cost ($)
§ 153.320	0938–1155	25	25	60	1,500	$121,880.00	$121,880.00
§ 153.630(b)(6)	0938–1155	70	2,800	1	2,800	432,194.00	432,194.00
§ 156.111(e)(1)	0938–1174	*10	10	4	40	2,641.60	2,641.60
§ 156.111(e)(2)	0938–1174	*10	10	19	190	15,208.00	15,208.00
§ 156.111(e)(3)	0938–1174	*10	10	12	120	7,924.80	7,924.80
§ 156.111(e)(4)	0938–1174	*10	10	12	120	7,924.80	7,924.80
§ 156.115(b)(2)(ii)	0938–1174	*5	5	0.5	2.5	165.10	165.10
§ 156.150	0938–1174	175	175	0.5	87.5	5,941.25	5,941.25
§§ 158.320–323, 158.340, 158.346–350	0938–1114	22	22	140	3,080	233,766.72	233,766.72
Total		302	3,067		7,940	827,646.27	827,646.27

*Denote the same entities. For purposes of calculating the total, the value is used only once.

Note: There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 12.

J. 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 the OMB.

To obtain copies of the supporting statement and any related forms for the final collections discussed above, please visit CMS's website at *www.cms.hhs.gov/PaperworkReductionActof1995*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this final rule and identify the rule (CMS–9930–F), the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due May 17, 2018.

V. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes standards related to the risk adjustment program for the 2019 benefit year, as well as certain modifications that will promote State flexibility and control over their insurance markets, reduce burden on stakeholders, and protect consumers from increases in premiums due to issuer uncertainty. The Premium Stabilization Rule and previous Payment Notices provided detail on the implementation of the risk adjustment program, including the specific parameters applicable for the 2014, 2015, 2016, 2017, and 2018 benefit years. This rule finalizes additional standards related to EHBs; cost-sharing parameters; QHP certification; the Exchanges, including terminations, exemptions, eligibility and enrollment; AV for stand-alone dental plans; MEC; the rate review program; the medical loss ratio program; the Small Business Health Options Program; and FFE and SBE–FP user fees.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)), 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year).

OMB has determined that this final rule is ''economically significant'' within the meaning of section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect of $100 million in any 1 year. Accordingly, we have prepared an RIA that presents the costs and benefits of this final rule.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule—(1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and a ''significant'' regulatory action is subject to review by OMB. HHS has concluded that this rule is likely to have economic impacts of $100 million or more in at least 1 year, and therefore, meets the definition of ''significant rule'' under Executive Order 12866. Therefore, HHS has provided an assessment of the potential costs, benefits, and transfers associated with this rule.

The provisions in this final rule aim to improve the health and stability of the Exchanges, and to provide States with additional flexibility and control over their insurance markets. They will reduce regulatory burden, and reduce administrative costs for issuers and States, and will lower net premiums for consumers. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to affordable health coverage. Although there is some uncertainty regarding the net effect on enrollment and premiums, we anticipate that the provisions of this final rule will help further HHS's goal of ensuring that all consumers have access to quality, affordable health care; that markets are stable; and that Exchanges operate smoothly.

Although it is difficult to discuss the wide-ranging effects of these provisions in isolation, the overarching goal of the premium stabilization, market standards, and Exchange-related provisions and policies in the PPACA is to make affordable health insurance available to individuals who do not have access to affordable employer-sponsored coverage or government-sponsored coverage. The provisions within this final rule are integral to the goal of expanding coverage. For example, the risk adjustment program helps prevent risk selection and decrease the risk of financial loss that health insurance issuers might otherwise expect in 2019.

HHS anticipates that the provisions of this final rule will help further the Department's goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed choices, that Exchanges operate smoothly, that the risk adjustment program works as intended, and that States have more control and flexibility over EHBs, QHP certification and the operation and establishment of Exchanges. Affected entities such as QHP issuers will incur costs to comply with the proposed provisions, for example, those related to the functions of a SHOP; including calculating the minimum participation rate at the employer level and processing SHOP enrollments for employers and employees; and States will incur costs if they select a new EHB-benchmark plan under the new regulations. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A–4, Table 13 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including providing consumers with access to affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify certain benefits of this final rule—such as any reduction in burden related to changes in the timing related to State deadlines for submission of rate filings from issuers that only offer non-QHPs; increased flexibility for Exchanges related to the removal of certain requirements for Navigator programs and non-Navigator assistance personnel entities; increased access to the direct enrollment pathway stemming from permitting a third-party entity to conduct operational readiness reviews for agents, brokers, and issuers; benefits to Exchanges related to proposed simplifications of verification requirements; benefits to consumers, issuers or Exchanges related to the changes related to the special enrollment periods; increased flexibility for States relating to the proposals regarding the SHOP enrollment process; and potential decreases in premiums to consumers related to removing actuarial value standards for SADPs—and certain costs—such as the costs incurred by small employers, agents and brokers, and potential increases in out-of-pocket costs to consumers related to removing actuarial value standards for SADPs; and costs to issuers, brokers, agents, and employers related to changes in SHOP enrollment procedures. The effects in Table 13 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers. The annualized monetized costs described in Table 13 reflect direct administrative costs to health insurance issuers as a result of the finalized provisions, and include administrative costs associated with States requesting a reduction in risk adjustment transfers for the State's individual, small group or merged market, the reduction in costs relating to issuers and States having to no longer submit rate increases for student health insurance plans to HHS, and costs associated with States seeking an adjustment to the MLR standard in the State's individual market that are estimated in the Collection of Information section of this final rule. The annual monetized transfers described in Table 13 include costs associated with SBE–FP user fees, the risk adjustment user fee paid to HHS by issuers, and reductions in rebate payments from issuers to consumers related to QIA and MLR adjustments. We are finalizing a risk adjustment user fee to collect $1.80 per enrollee per year from risk adjustment issuers to operate the risk adjustment program on behalf of States, which we expect to cost

approximately $40 million, similar to the $40 million in contract costs expected for benefit year 2018 when we established a $1.68 per-enrollee-per-year risk adjustment user fee rate. As in 2018, the risk adjustment user fee contract costs for 2019 include additional costs for risk adjustment data validation; however, we expect reduced costs related to issuer outreach and education as issuers gain familiarity with the risk adjustment program, and lower enrollment in risk adjustment covered QHPs, and additional costs to include administrative and personnel costs related to the risk adjustment program that were inadvertently excluded in prior years' cost estimation, which together results in a slightly higher risk adjustment user fee rate than the benefit year 2018 rate. As we generally expect similar risk adjustment user fee costs as the 2018 benefit year, there are no changes to the risk adjustment user fee transfers to include in Table 13. Also, we expect a decrease in FFE user fee collections necessary as we estimate lower contract costs due to streamlining of FFE operations and an increase in premiums but also lower enrollment, resulting in a proposed user fee rate of 3.5 percent for 2019, which is the same as the FFE user fee rate established for 2014 through 2018 benefit years. However, the decrease in user fee collections required to support FFE functions for the 2019 benefit year will be similar to the updated costs for the 2018 benefit year, and the user fee rate will yield the same amount of transfers from FFE issuers to the Federal government as in the prior benefit year. Therefore, there are no changes to the FFE user fee transfers to include in Table 13. We also proposed an SBE–FP user fee rate to be set at 3.0 percent for benefit year 2019, which is higher than the 2.0 percent SBE–FP user fee rate we finalized for the 2018 benefit year. In this rule, we also finalized a proposal to cease charging user fees on SHOP issuers offering plans through an FFE or SBE–FP starting for plan years beginning on and after January 1, 2018.

TABLE 13—ACCOUNTING TABLE

Benefits:

Qualitative:
- Greater market stability resulting from improvements to the risk adjustment methodology.
- Potential increased enrollment in the individual market stemming from lower premiums, leading to improved access to health care for the previously uninsured, especially individuals with medical conditions, which will result in improved health and protection from the risk of catastrophic medical expenditures.[a]
- More informed Exchange QHP certification decisions.
- Increased coverage options for small businesses and employees with less adverse selection.
- Cost savings to consumers and issuers due to reduced administrative costs for issuers.
- Potential decreases in premiums associated with States opting to select a new EHB-benchmark plan.
- Reduced burden to Exchanges, due to the removal of the requirements that each Exchange must have at least two Navigator entities, and that one of these entities must be a community and consumer-focused nonprofit group, and the removal of the requirement that each Navigator (and each non-Navigator entity subject to § 155.215) maintain a physical presence in the Exchange service area.
- Reduced costs and burden and increased flexibility to agents and brokers performing direct enrollment and their third-party auditors due to the removal of the requirement to obtain HHS approval to perform reviews.
- Reduction in administrative costs to issuers due to the removal of the meaningful difference standard, and final changes to the SHOPs.

Costs:	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized ($/year)	−$26.71	2016	7	2018–2022
	−25.54	2016	3	2018–2022

Quantitative:
- Costs incurred by issuers and States to comply with provisions in the final rule as detailed in the Collection of Information Requirements section, taking into account the reduction in burden and costs for issuers and States due to the elimination of the requirement to submit rate reviews to HHS for student health insurance coverage[b] and increase in the rate review threshold and the reduction in burden and costs to States related to the requests for adjustment to the MLR standard in their individual markets.
- Reduction in costs to issuers due to changes to the requirements for risk adjustment data validation.
- Reduction in potential costs to Exchanges since they will no longer be required to conduct sampling as a verification process for eligibility for employer-based insurance starting plan year 2018, and can instead conduct an alternate process through plan year 2019.
- Costs incurred by Exchanges to implement new verification requirements for income inconsistencies.
- Regulatory familiarization costs.

Qualitative:
- Costs due to increases in providing medical services (if health insurance enrollment increases).
- Costs to issuers of redesigning SADPs to account for the removal of actuarial value standards for SADPs.
- Potential increases in out of pocket costs associated with States opting to select a new EHB-benchmark plan.
- Potential increases in out of pocket costs and loss of benefits and services associated with substitution between EHB categories.[c]
- Potential increase in consumer burden related to plan comparisons in those States allowing substitution between EHB categories.

Transfers:	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Federal Annualized Monetized ($/year)	$17.8	2017	7	2018–2022
	18.6	2017	3	2018–2022
Other Annualized Monetized ($/year)	87	2017	7	2018–2022
	87	2017	3	2018–2022

Costs:	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Quantitative:				
• Transfer from health insurance issuers to the Federal government of $40 million as risk adjustment user fees for 2022 (the same amount as previously estimated for 2018–2021).				
• Increased transfers from SBE–FP issuers to the Federal government of $20 million due to increase in user fee rate from 2.0 set in 2018 to 3.0 percent final for 2019.				
• Decrease in user fee transfers from SHOP issuers offering plans through an FF–SHOP or SBE–FP for SHOP to the Federal government of approximately $6 million in 2019.				
• Reduced transfers to consumers from health insurance issuers in the form of rebates of $75 million to $87 million due to final amendments to the medical loss ratio requirements.[d]				
Qualitative:				
• Lower premium rates in the individual market due to the improved risk profile of the insured, competition, and pooling.				
• A decrease in the premiums and risk adjustment transfers in the individual, small group or merged markets as a result of potential State requests to reduce risk adjustment transfers for the State's individual, small group or merged market.				
• Potential increases in premiums associated with adjustments to MLR.				
• Potential decreases in premiums associated with removal of AV standards for SADPs.				
• Potential increases in out of pocket costs associated with removal of AV standards for SADPs.				

[a] Removal of AV standards for SADPs may reduce enrollment due to reductions in coverage and potential higher out-of-pocket costs.
[b] The reduction in burden and costs associated with student health insurance could result in lower premiums.
[c] Some consumers may experience an increase in services and benefits. The net result is uncertain.
[d] For the purpose of calculating total transfers, the upper bound was used.

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the PPACA's impact on Federal spending, revenue collection, and insurance enrollment. The PPACA transitional reinsurance program and temporary risk corridors program end after the benefit year 2016. Therefore, the costs associated with those programs are not included in Tables 14 or 15 for fiscal years 2019–2022. Table 14 summarizes the effects of the risk adjustment program on the Federal budget from fiscal years 2018 through 2022, with the additional, societal effects of this final rule discussed in this RIA. We do not expect the provisions of this final rule to significantly alter CBO's estimates of the budget impact of the premium stabilization programs that are described in Table 14. We note that transfers associated with the risk adjustment program were previously estimated in the Premium Stabilization Rule; therefore, to avoid double-counting, we do not include them in the accounting statement for this final rule (Table 13).

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that the quantitative effects of the provisions proposed in this rule are consistent with our previous estimates in the 2018 Payment Notice for the impacts associated with the APTC, the premium stabilization programs, and FFE user fee requirements.

TABLE 14—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT, REINSURANCE, AND RISK CORRIDORS PROGRAMS FROM FISCAL YEAR 2018–2022

[In billions of dollars]

Year	2018	2019	2020	2021	2022	2018–2022
Risk Adjustment, Reinsurance, and Risk Corridors Program Payments	5	5	5	6	6	27
Risk Adjustment, Reinsurance, and Risk Corridors Program Collections*	5	5	6	6	6	28

Note 1: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time.
Note 2: The CBO score reflects an additional $1 million in payments in FY 2018 that are collected in prior fiscal years. CBO does not expect a shortfall in these programs.
Source: Congressional Budget Office. *Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2017 to 2027* Table 2. September 2017. Available at *https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/53091-fshic.pdf*.

1. Risk Adjustment

The risk adjustment program is a permanent program created by the PPACA that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. We established standards for the administration of the risk adjustment program, in subparts D and G of part 153 in Title 45 of the CFR.

A State approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. As described in the 2014 through 2018 Payment Notices, if HHS operates risk adjustment on behalf of a State, it will fund its risk adjustment program operations by assessing a risk adjustment user fee on issuers of risk adjustment covered plans. For the 2019 benefit year, we estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for 2019 will be approximately $40 million, and that the risk adjustment user fee would be approximately $1.80 per enrollee per year. This user fee reflects costs to support the risk adjustment data validation process in 2019, lower costs related to risk adjustment issuer outreach and education and lower enrollment in risk adjustment covered QHPs, and includes administrative and personnel cost related to the risk adjustment program, resulting in a slightly higher user fee rate for 2019 than the 2018 benefit year rate.

We believe that the approach of blending the coefficients calculated from the 2016 benefit year enrollee-level EDGE data with 2014 and 2015 MarketScan® data finalized in this rule will provide stability within the risk adjustment program and minimize volatility in changes to risk scores from the 2018 benefit year to the 2019 benefit

year due to differences in the datasets' underlying populations.

We are finalizing the provision for States to request a reduction in risk adjustment transfers in the individual, small group or merged market. We expect this policy will reduce transfers proportional to the percent by which the States seek to reduce the transfers to account for State-specific market rules or relevant factors without the necessity for States to undertake operation of their own risk adjustment program. However, because the risk adjustment program is budget neutral, any State decision to request a reduction in the risk adjustment transfers will have no net impact on risk adjustment transfers.

2. Risk Adjustment Data Validation

We are finalizing several changes to the requirements for risk adjustment data validation that overall would reduce regulatory burden and costs for issuers of risk adjustment covered plans. HHS believes that adjusting issuers' risk adjustment risk scores only when an issuer's failure rate for a group of HCCs is statistically different from the weighted mean failure rate for that group of HCCs for all issuers that submitted initial validation audits will help market stability by increasing issuers' ability to predict risk adjustment transfers and liquidity needs. We anticipate that many issuers required to participate in risk adjustment data validation will not have their risk scores adjusted, based on our analysis of error rates in the Medicare risk adjustment data validation program.

We anticipate that the post-transfer adjustment of risk adjustment transfers for issuers that exited a State market will result in transfer adjustments for a small subset of issuers that previously would not have had their transfers adjusted, but HHS does not expect this policy to increase burden for these issuers, especially in light of the revised payment adjustments for error rates policy finalized in this rule.

HHS estimates that not requiring issuers that have 500 or fewer billable member months Statewide to conduct an initial validation audit beginning in the 2017 benefit year will reduce the administrative burden and costs on those issuers. The reduction in burden and costs related to this ICR has been discussed previously in the Collection of Information Requirements section.

Under the change to the sampling methodology finalized in this rule, issuers that were the sole issuer in a risk pool will still need to provide a sample for data validation, but the sample will not include enrollees from the risk pool where they were the sole issuer. Therefore, this change will not have a significant impact on costs or burden for affected issuers.

We are finalizing an amendment to § 153.630(b)(6) to state that a qualified provider licensed to diagnose mental illness that is prohibited by State privacy laws from furnishing a complete medical record for data validation may furnish a signed mental or behavioral health assessment that providers routinely prepare along with the required attestation. For risk adjustment data validation purposes, a mental or behavioral health assessment should, to the extent permissible under applicable State and Federal privacy laws, contain: (i) The enrollee's name; (ii) sex; (iii) date of birth; (iv) current status of all mental or behavioral health diagnoses; and (v) dates of service. The burden associated with this requirement has been discussed previously in the Collection of Information Requirements section.

We are finalizing an amendment to § 153.630(b)(9) to state that, if an issuer of a risk adjustment covered plan (1) fails to engage an initial validation auditor; (2) fails to submit the results of an initial validation audit to HHS; (3) engages in misconduct or substantial non-compliance with the risk adjustment data validation standards and requirements applicable to issuers of risk adjustment covered plans; or (4) intentionally or recklessly misrepresents or falsifies information that it furnishes to HHS, HHS may impose CMPs in accordance with the procedures set forth in § 156.805(b) through (e). Because risk adjustment data validation has thus far operated as a pilot program, we cannot estimate the number of issuers that will be subject to CMPs. However, we do not expect that a significant number of issuers will engage in the extreme misconduct required to warrant a CMP under this amended regulation.

3. Rate Review

We are amending § 154.103 to exclude student health insurance coverage effective on or after July 1, 2018 from the Federal rate review requirements. This will reduce burden related to rate review submission and review for issuers and States. In addition, providing States with more flexibility regarding timing of submission of rate filing justification from issuers that offer non-QHPs only, and reducing the advance notification requirement for rate increase announcements, will reduce regulatory burden for issuers and States. The reduction in burden and costs related to ICRs have been discussed previously in the Collection of Information Requirements section.

Raising the Federal default review threshold from 10 percent to 15 percent will reduce administrative burden for issuers and States while continuing to provide the Secretary and the States with the information necessary to effectively carry out their responsibilities to monitor rate increases inside and outside of Exchanges. As discussed previously in the Collection of Information Requirements section, issuer burden will decrease by an estimated $20,576 and the State burden will decrease by an estimated $519,674 annually. Given that only one rate filing subject to review over the last 4 years in the 10 to 15 percent rate increase range was determined to be unreasonable, we feel this is a reasonable tradeoff for the potential burden savings.

4. Additional Required Benefits (§ 155.170)

We are extending the applicability of the policies governing State-required benefits at § 155.170 to the policies finalized at § 156.111, which provide States with new options for selecting their EHB-benchmark plans beginning for the 2019 plan year. Specifically, under any of the three EHB-benchmark plan selection options, or if the State defaults to its current EHB-benchmark plan, the policies regarding State-required benefits will continue to apply. Because these policies continue to be in effect, we do not anticipate any additional burden on States or issuers.

5. Standards for Navigators and Certain Non-Navigator Assistance Personnel (§§ 155.210 and 155.215)

We amended § 155.210(c)(2) to remove the requirements that each Exchange must have at least two Navigator entities and that one of these entities must be a community and consumer-focused nonprofit group. We also amended §§ 155.210(e)(7) and 155.215(h) to remove the requirements that Navigators and non-Navigator assistance personnel entities subject to those regulations maintain a physical presence in the Exchange service area. These amendments to § 155.210(c)(2) will reduce the burden on Exchanges to have at least two separate Navigator entities, and as a result, Exchanges may be able to reduce funding amounts while still meeting program requirements. Removing these requirements will help promote flexibility and autonomy for each Exchange to structure its Navigator program, and to award grant funding to the number and type of entities that will be most effective and efficient for that specific Exchange service area. To the

extent that Exchanges take advantage of these flexibilities, consumers may have fewer options of Navigator grantees and may not have access to a Navigator grantee or a non-Navigator assistance personnel entity that maintains a physical presence in the Exchange service area. Exchanges continue to have the flexibility to fund more than one Navigator grantee and State Exchanges continue to have the flexibility to require that Navigators maintain a physical presence in the Exchange service area.

6. Standards for Third-Party Entities To Perform Audits of Agents, Brokers, and Issuers Participating in Direct Enrollment (§ 155.221)

The final regulations replace the requirement that an HHS-approved third party perform audits of agents and brokers participating in direct enrollment and use their own internet website for QHP selection or to complete the Exchange eligibility application to instead permit an agent, broker or issuer to select a third-party entity that meets HHS requirements to conduct an annual operational readiness review prior to participating in direct enrollment. HHS anticipates this approach will reduce the regulatory burden on agents, brokers, and issuers participating in direct enrollment. HHS also anticipates these changes will reduce the burden on third-party auditors performing reviews under § 155.221, as those entities will no longer be required to obtain HHS approval to perform the reviews. Furthermore, we believe this policy will expand the available number of qualified third-party auditors by removing any time and operational restrictions imposed by the HHS pre-approval requirement, which will provide more flexibility to agents, brokers, or issuers as they complete operational readiness reviews. Additionally, we believe this will enable more agents, brokers and issuers to demonstrate operational readiness by reducing the burden on HHS for conducting reviews, expediting the ability of these entities to demonstrate readiness, and increasing the feasibility of approval for use of innovative pathways, thereby creating more opportunities for enrollment in QHP coverage for consumers, potentially increasing enrollment. HHS anticipates that some of the burden will be lessened by the fact that many agents, brokers, or issuers already have the established privacy and security controls, and may have existing relationships with auditors that could be leveraged for these reviews. We intend to provide additional technical details regarding compliance with the specific requirements under these rules in guidance in the future.

7. Eligibility Standards (§ 155.305)

The requirement in § 155.305(f)(4)(ii) that the Exchange must send direct notification to the tax filer before denying eligibility for APTC to consumers who fail to file and reconcile went into effect in mid-January 2017; therefore, it did not impact operations for the 2017 open enrollment period, which was nearly over then. At that point in time, for the FFE, the household contacts for non-filers had been notified of their tax filer's non-compliance, and APTC had been discontinued at auto re-enrollment for those who did not file a Federal income tax return according to IRS data or inform the FFE that they had filed a Federal tax return and reconciled past APTC. Requiring the Exchange to deny APTC for failure to file and reconcile even in the absence of ''direct notification . . . to the tax filer'' is unlikely to add new burden since Exchanges have not yet implemented § 155.305(f)(4)(ii). We do not believe that Exchanges have built an FTI-compliant noticing infrastructure since the publication of the final rule establishing § 155.305(f)(4)(ii) that they will need to dismantle. However, removing § 155.305(f)(4)(ii) avoids significant costs for Exchanges that, as discussed above, no longer must build the infrastructure necessary to directly notify tax filers about their tax filing status while protecting FTI.

8. Verification Requirements (155.320)

This rule amends § 155.320(c)(3)(iii) to create annual income data matching issues when applicants attest to income above 100 percent FPL, but trusted data sources show income below 100 percent FPL. We estimate that each SBE will incur one-time costs of approximately $450,000 to complete the necessary system changes to implement this policy. For 12 SBEs, the estimated total cost will be $5.4 million. This estimate does not take into account the ongoing operational expenses of processing data matching issues from this new requirement. Ongoing operational costs will be dependent on the Exchange's number of applicants with income inconsistencies and the threshold for setting a data matching issue.

This final rule will amend § 155.320(d)(4) to allow an Exchange to conduct an HHS-approved alternative process instead of sampling, as provided under paragraph (d)(4)(ii) through benefit year 2019. We believe this will relieve Exchanges from the burden of investing resources to conduct sampling when the FFEs' study of a sampling-like process found that this method of verification may not be cost-effective for some Exchanges at this time. We estimate the burden associated with sampling based in part on the alternative process used for the FFEs. HHS incurred approximately $750,000 in costs to design and operationalize this study and the study indicated that $353,581 of APTC was potentially incorrectly granted to individuals who inaccurately attested to their eligibility for or enrollment in a qualifying eligible employer-sponsored plan. We placed calls to employers to verify 15,125 cases but were only able to verify 1,948 cases. A large number of employers either could not be reached or were unable to verify a consumer's information, resulting in a verification rate of approximately 13 percent. The sample-size involved in the 2016 study did not represent a statistically significant sample of the target population and did not fulfill all regulatory requirements for sampling under paragraph (d)(4)(i) of § 155.320.

Taking additional costs into account—namely, the cost of sending notices to employees as required under paragraph (d)(4)(i)(A), the cost of building the infrastructure and implementing the first year of operationalizing this process, and the cost of expanding the number of cases to a statistically significant sample size of approximately 1 million cases—we estimate that the overall cost of implementing sampling would be approximately $8 million for the FFE, and between $2 million and $7 million for other Exchanges, depending on their enrollment volume and existing infrastructure. Therefore, we estimate that the average per-Exchange cost of implementing sampling that resembles the FFE's approach would be approximately $4.5 million for a total cost to SBEs of $54 million, when assuming 12 SBEs (operating in 11 States and the District of Columbia). This cost estimate does not, however, take into account the cost of notifying consumers when the information provided by their employer changes their eligibility determination described under paragraph (d)(4)(i)(E), the cost of providing employees consumer support that may be needed to understand notices and any change in eligibility, or the cost of ending those consumers' APTCs, when necessary. This estimate also does not account for the unique operating costs of each Exchange, the change to paragraph (d)(4) to allow

Exchanges to continue to use an alternate process through benefit year 2019, and the flexibility afforded Exchanges described at § 155.315(h) and referenced in § 155.320(a)(2).

We believe this finalized change will lessen the financial and technical burdens on Exchanges under current regulation and allow Exchanges to conduct an alternative process to sampling under paragraph (d)(4) as approaches to sampling are refined and data bases are compiled over time. We sought comment on the reduction in burden associated with extending the option to allow Exchanges to fulfill verification requirements by conducting an HHS-approved alternative process to sampling through plan year 2019. We did not receive any comments on the reduction of burden associated with our proposed change.

9. Special Enrollment Periods (§ 155.420)

We do not anticipate that the revisions to § 155.420 will create significant costs or burdens because several changes will simplify special enrollment period policy, and we also believe that they will generate some benefit in the form of added efficiency for Exchanges and improvements in some consumers' ability to maintain continuous coverage and understand their coverage options.

For example, the amendment to paragraph (d)(1)(iii) allows Exchanges to provide similar treatment to all women losing non-MEC pregnancy-related coverage, which enables a more streamlined special enrollment period eligibility process.

Additionally, the revisions in paragraph (b)(2)(i) align regulatory policy for special enrollment periods based on a court order with other similar special enrollment period types, and create operational efficiencies for Exchanges by streamlining effective date options across similar special enrollment periods with qualifying events related to gaining or becoming a dependent. For example, this revision to the regulation will enable the FFE to use a simpler online, automated application pathway for more special enrollment period-eligible consumers, meaning that fewer consumers will need to use a manual and costly casework process to use their special enrollment period. For limited cases when casework support is required, operations would also be simplified.

We acknowledge that this may not be the case for all Exchanges, and that an Exchange that has automated the option for consumers to elect that their coverage take effect on the first of the month after the date of their qualifying event may need to make updates so that consumers instead have the option to elect that their coverage take effect the first of the month after their date of plan selection. However, as discussed in the preamble, we believe that this burden will be limited, and mitigated due to the fact that offering a ''first of the month'' coverage effective date is optional for Exchanges, permitting a delayed rollout if necessary.

Additionally, amending paragraph (a)(5) to exempt qualified individuals from the prior coverage requirement that applies to certain special enrollment periods if they lived in a service area where no qualified health plan was available through the Exchange for 1 or more days during the 60 days preceding the qualifying event or during their most recent preceding enrollment period, as specified in §§ 155.410 and 155.420, may provide a pathway to coverage for a small group of individuals, and is not anticipated to impact the Exchange risk pool. It may generate burden on Exchanges due to required technical and operational updates should it become necessary to implement, but we anticipate that this burden will be mitigated by the small size of the affected group and by practices that are already in place in many Exchanges to verify eligibility for special enrollment periods. Additionally, Exchanges already exempt qualified individuals from the prior coverage requirement who may not previously have had access to QHP coverage through an Exchange, including those who were previously living in a foreign country or United States territory and Indians as defined by section 4 of the Indian Health Care Improvement Act. Therefore, we do not believe that adding an additional small population to this exemption will create additional costs or burdens.

Finally, because simplified special enrollment period eligibility policy provides improved pathways to continuous coverage for special enrollment period-eligible consumers, we anticipate that the provisions in this rule may result in less burden on call center representatives and caseworkers related to fewer questions about special enrollment periods due to gaining or becoming a dependent and loss of certain types of pregnancy-related coverage. We also anticipate that the revisions will reduce burden on consumers, have a positive effect on the risk pool, and not result in additional costs or burdens for issuers.

In addition, some States that operate Exchanges expressed concern that amending the plan option restrictions available to dependents who are newly enrolling in a plan with a QHP enrollee through a special enrollment period will increase the burden on States, which will be required to do a system build to align their systems with this change. We appreciate these concerns raised by States, but do not anticipate that this change will add significant additional burden on top of the system builds States are already doing. The intent of this policy change is to streamline the plan option rules for dependents who are newly enrolling in coverage with enrollees through a special enrollment period and so we anticipate that any additional burden incurred to amend Exchange system functionality will be offset by the efficiencies gained in streamlining Exchange eligibility rules.

10. Effective Dates for Terminations (§ 155.430)

Permitting all enrollee-initiated terminations to become effective on the date of enrollee request or a later date of their choosing, and removing the special termination effective date for newly eligible Medicaid/CHIP/BHP consumers streamlines termination effective dates for Exchanges and reduces complication and confusion among consumers and issuers. Exchanges and issuers were not expected to incur new costs by aligning these termination dates, as Exchanges and issuers are well acquainted with same-day termination transactions. However, we received comments from some SBEs that their systems would not allow for mid-month terminations. Therefore, we are not requiring the alignment of termination effective dates as proposed, but rather are providing Exchanges flexibility to choose whether to implement the changes that were proposed. Operationalizing the aligned termination dates may reduce system errors and related casework, as well as confusion for consumers, issuers, and caseworker and call center staff based on contradictory rules for different scenarios.

11. Eligibility Standards for Exemptions (§ 155.605)

We do not anticipate that the amendment to § 155.605(d) will create additional costs or burdens. The amendment to § 155.605(d)(2)(iv) will enable the Exchanges to process the consumer's exemption from the individual shared responsibility provision due to lack of affordable coverage based on projected income, for those not eligible for employer-sponsored coverage, when there is no bronze plan available by allowing the Exchanges to process the consumer's

exemption based on the lowest cost Exchange metal level plan, excluding catastrophic coverage, available in the individual market through the Exchange in the State in the county in which the individual resides. This policy will not increase the burden on consumers or Exchanges. Without these revisions, individuals may lack access to qualifying or affordable health coverage, but be unable to qualify for an exemption from the individual shared responsibility provision to purchase qualifying health coverage and the associated financial penalty due to the lack of coverage in their area or the inability to calculate whether coverage is unaffordable. This policy will also not result in additional costs or burdens for issuers.

12. Small Business Health Options Program (Part 155, Subpart H, § 155.200, §§ 156.285 and 156.286, § 156.350, §§ 157.205 and 157.206)

HHS is finalizing the proposal to grant additional flexibilities, for plan years beginning on or after January 1, 2018, to small employers enrolling in SHOP QHPs and to participating QHP issuers in how they interact with a SHOP. These changes will be effective as of the effective date of the final rule and the FF–SHOPs and SBE–FPs for SHOP will operate under the new enrollment approach. Under this final rule, several existing requirements on SHOPs will not apply for plan years beginning on or after January 1, 2018, allowing State Exchanges the flexibility to operate their SHOP in a way that makes sense for the small businesses in their State, with reduced limitations imposed by Federal regulation. The FF–SHOPs and SBE–FPs for SHOP will take advantage of the flexibility of the enrollment approach described through this final rule and operate in a leaner fashion. Under the approach being finalized, SHOPs are no longer required to enroll small groups in SHOP QHPs through a SHOP website. Instead, small employers will, in SHOPs that operate under this approach, enroll through a participating QHP issuer, or a SHOP-registered agent or broker.

HHS believes that the changes will reduce burden on participating QHP issuers, small employers, and agents and brokers for several reasons. Under the approach being finalized, for plan years beginning on or after January 1, 2018, effective on the effective date of this rule, participating QHP issuers will, in SHOPs that operate under the new flexibilities like the FF–SHOPs and SBE–FPs for SHOP, enroll small groups through their existing enrollment channels—utilizing their existing technologies and processes. Small groups enrolled in SHOP QHPs for plan years before January 1, 2018 will not be affected by the proposed changes to enrollment through a SHOP until they are due to renew in a SHOP QHP for the 2018 plan year. While some additional requirements will be imposed onto issuers, HHS anticipates that any additional burden on issuers as a result of the changes in this rule will be negated in an ultimate net reduction in burden as many Federal regulations are being removed and any additional requirements onto issuers mainly consist of practices they currently perform in the private market.

In the 2018 Payment Notice, HHS finalized the removal of a participation provision that had required certain QHP issuers to participate in an FF–SHOP in order to participate in an FFE. As a result, there has been a significant decrease in the number of issuers in the FF–SHOPs in the 2018 plan year and therefore, HHS also expects fewer enrollments in the FF–SHOPs for plan year 2018. As of January 1, 2017, approximately 7,554 employer groups were enrolled in the FF–SHOPs, covering 38,749 lives. With the anticipated significant decreases in QHP issuer participation for enrollment beginning in 2018, it is not cost effective for the Federal government to continue to maintain certain FF–SHOP functionalities, collect significantly reduced user fees on a monthly basis, maintain the technologies required to maintain an FF–SHOP website and payment platform, generate enrollment and payment transaction files, and perform enrollment reconciliation.

Under the approach being finalized in this rule, issuers will still be subject to their State requirements, and HHS will minimize Federal requirements related to SHOP plans (that is, notice requirements, etc.) for plan years beginning on or after January 1, 2018. For example, issuers are often required by State law to generate enrollment and payment notices, and will continue to generate any State-required notices under the new SHOP enrollment approach. Under the proposed approach, the FF–SHOPs and SBE–FPs for SHOP will no longer generate enrollment notices, but the notice requirements for the FF–SHOPs and SBE–FPs for SHOP will not necessarily be transferred directly to participating QHP issuers. HHS can imagine a scenario where an issuer might generate an additional notice to a SHOP consumer that they are not required by Federal law to send, but may be required by State law, to send.

Issuers will still be required to accept enrollment from employers that offer their employees a choice of plans. HHS can foresee a circumstance where an employer offers its employees a choice of plans, across plan categories, and where the employees choose to enroll in plans offered by multiple issuers. In this circumstance, it will also be possible that an issuer will receive one application for enrollment from a group. Under the approach to SHOP enrollment being finalized, the issuer will be required to accept that single enrollment so long as the employer's group has met the minimum participation rate for their State, or is enrolling between November 15 and December 15, when the minimum participation rate rules do not apply. With the decrease in issuer participation in the SHOPs beginning in plan year 2018, HHS believes that a circumstance, similar to the one discussed above may occur. In the absence of premium aggregation functions, issuers, under the approach being finalized will be working directly with an employer, or their appointed SHOP-registered agent or broker for matters of enrollment and premium billing and payment. Under the new regulations, effective as of the effective date of this rule, issuers will be required to enroll consumers into plans, even if only one employee of a group wants to enroll. Further, issuers will also be required to process enrollments into SHOP QHPs, and, handle appeals (other than appeals related to employer eligibility), administer special enrollment periods and terminations. Issuers will still be subject to the market wide effective dates outlined in § 147.104(b)(1)(i)(C). While HHS believes that issuers currently perform the majority of these tasks, issuers may experience an increase in burden as it relates to the volume of consumers enrolling in their SHOP QHPs. Overall, HHS believes that under this approach, issuers will see a net cost savings, as their business processes for SHOP enrollments may be more closely aligned with their current business practices for enrollments outside the SHOP, and they will no longer be remitting user fees for FF–SHOP and SBE–FP SHOP enrollments.

As noted, SHOPs will be given the flexibility to adopt an enrollment approach through which enrollments occur directly with issuers or SHOP-registered agents or brokers, to continue to operate with the same functionalities as they currently do or to develop new practices as permitted by the proposals in this rule. In any case, SHOPs will need to meet only the regulatory minimums outlined in this final rule, therefore minimizing the overall amount

of regulatory requirements that SHOPs will otherwise need to meet. HHS believes that the new flexibility for SHOPs will result in an overall reduction in burden and cost for States operating their own SHOPs because we are providing States with the flexibility to pursue the enrollment approach that best meets their needs, because we are reducing the overall regulatory requirements for the SHOP Exchanges, and for the same reasons described above regarding why the enrollment approach being finalized will reduce burdens on the FF–SHOP and its stakeholders.

Under the new enrollment approach for SHOP plan years beginning on or after January 1, 2018, HHS believes that employers seeking to purchase coverage through an FF–SHOP or SBE–FP for SHOP will experience a reduction in regulatory burden related to enrollment, despite the fact that they may be required to visit at least two websites (the SHOP website and the issuer's website) prior to completing an enrollment in SHOP coverage as they will be able to enroll in coverage through a SHOP-registered agent or broker or through a participating QHP issuer—using issuers' streamlined enrollment technologies. Employers will also be required, as described throughout this document to notify their QHP issuer of their eligibility to purchase a SHOP QHP and of their ineligibility, if their eligibility were to be revoked. Employers will also be required to inform the SHOP if they become ineligible to participate in a SHOP, or choose to withdraw their eligibility, unless the issuer is notified by the SHOP. We believe this is still less cumbersome than the existing eligibility and enrollment process.

Under the flexibilities being finalized with this rule, some employers, specifically those who offer their employees a choice of plans, will experience an increase in administrative burden with the removal of a SHOP's premium aggregation functions. Without a SHOP's premium aggregation functions, employers will have to collect the enrollment and payment information needed from each of the issuers whose plans the employer intends to offer to its employees. In the event employees select plans from multiple insurance companies, the employer will be responsible for distributing the applications for enrollment to the individual issuers, collecting payments from the employees and sending the individual payments to each issuer. Due to the decrease in issuer participation in the FF–SHOPs, some SHOP employers only have one issuer offering FF–SHOP plans in their area and will not be able to offer their employees a choice of plans across issuers. In addition, historically, a majority of employers have not offered employee choice across different issuers. Therefore HHS does not believe the potential increased burden in this area due the removal of premium aggregation functions to be significant. Employers will still be able to view a listing of all of the SHOP QHPs available, by plan category and issuer on a SHOP website. HHS expects that the actual process of enrolling in SHOP QHPs under this approach will be less burdensome than the existing enrollment approach through a SHOP website. As previously mentioned, HHS anticipated significantly lower issuer participation for the SHOP in the 2018 plan year. A decrease in issuer participation unfortunately also results in less choice for consumers. While employers may experience an increase in burden, especially if offering employees a choice of plans, under the new flexibilities for SHOPs, HHS anticipates the benefits of the finalized approach will ultimately outweigh the minimal additional costs employers could face.

Further, the Federal government will experience a dramatic reduction in the role it plays in operating an FF–SHOP and the contract support that it requires in order to support it. In 2016, the cost of running the FF–SHOP website (utilized by both FF–SHOPs and SBE–FPs for SHOP) was approximately $30 million, and HHS expects annual expenditures to drop significantly—by at least 90 percent—within a few years, as it responsibly wind-downs the integration of the FF–SHOPs.

13. User Fees (§ 156.50)

To support the operation of FFEs, we require in § 156.50(c) that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE. In this final rule, for the 2019 benefit year, we set the monthly FFE user fee rate at 3.5 percent of the monthly premium, and the monthly SBE–FP user fee rate at 3.0 percent of the monthly premium. This increase in SBE–FP user fee rate from 2.0 percent in 2018 to 3.0 percent in 2019 will increase transfers from SBE–FP issuers to the Federal government by $20 million. Additionally, we will cease charging monthly user fees to SHOP issuers offering plans through an FF–SHOP or SBE–FP SHOP for plan years beginning on and after January 1, 2018, effective on the effective date of the final rule. This will decrease user fee transfers from SHOP issuers offering plans through an FFE or SBE–FP by approximately $6 million.

14. Provision of EHB

Under § 156.111, we provide States with more flexibility by offering States three new methods for selecting their State EHB-benchmark plans. Under this policy, if the State does not select one of the three methods for changing its EHB-benchmark plan, the State will default to its current EHB-benchmark plan. We recognize that, to the extent that States take advantage of the EHB-benchmark plan selection options at § 156.111, States and issuers will experience an increase in burden to develop new policies and implement new plan designs. We anticipate that most States will need to invest resources to analyze the three new EHB-benchmark selection options to make an informed selection, even if the State ultimately defaults. Several States may select one of the new options, and will need additional resources to facilitate a public notice and comment period and develop and submit the necessary documents specified by HHS (including the requisite actuarial certification) to effectuate the State's selection. Additionally, in States that choose to select their EHB-benchmark plan under any of the three available options, issuers offering plans that provide EHB will incur additional administrative costs associated with designing plans compliant with the State's newly selected EHB-benchmark plan.

Due to the many PPACA policies directly or indirectly tied to EHB, HHS recognizes the impact this policy will have on parties beyond issuers required to provide EHB-compliant plans. For example, the State's new EHB-benchmark selection can impact how issuers set their annual limitation on cost sharing and how issuers determine which benefits may not be subject to annual and lifetime dollar limits.[104]

It is our aim that the flexibility under the policy will allow for States and issuers to be more innovative in designing benefit structures that will ultimately affect affordability for consumers. However, we realize that

[104] The definition of EHB also has an impact on the annual limitation on cost sharing at section 1302(c) of the PPACA (which is incorporated into section 2707(b) of the PHS Act) and the prohibition of annual and lifetime dollar limits at section 2711 of the PHS Act, as added by the PPACA.

this policy will have varying impact on consumers depending on how a State chooses to implement the policy. Consumers enrolled in individual and small group market plans will be affected by changes to EHB in that their benefits may change and in some cases premiums may increase or decrease depending upon State implementation of the policies. Additionally, in States that use one of the methods to select a new EHB-benchmark plan, the new EHB-benchmark plan selection may impact the amount of PTC and CSRs for enrollees in the State. For these consumers, subsidies will increase or decrease when compared to their State's current EHB-benchmark plan. PTC is available only for that portion of a plan's premium attributed to EHB. To the extent that a State's EHB-benchmark plan, under the policy, leads to lower premiums for the second lowest cost silver plan, PTC will be reduced, but not the percent of income a consumer with PTC is expected to contribute to their premium. This effect will represent a transfer from consumers who receive PTC to the Federal government. Individual and small group market enrollees who do not receive PTC will experience lower premiums for less comprehensive coverage that can result in more affordable coverage options but possibly higher out-of-pocket costs for the consumer.

We anticipate that States are more likely to select EHB-benchmark plans under this policy such that premiums have the potential to be reduced in the long-term to achieve affordability in benefit design. However, even with the generosity standard now being applied to all of the EHB-benchmark selection options, the policy may provide some ability for States, depending on the State, to select EHB-benchmark plans in a manner that will increase premiums. To the extent that a State's EHB-benchmark plan leads to higher premiums for the second lowest cost silver plan, PTC will be increased.

Consumers who have specific health needs may also be affected by the policy. In the individual and small group markets, depending on the selection made by the State in which the consumer lives, consumers with less comprehensive plans may no longer have coverage for certain services. In other States, again depending on State choices, consumers may gain coverage for some services.

As explained above, HHS anticipates that § 156.111 will generate additional costs for States, issuers, and certain consumers in the short run. However, although we are uncertain as to how States will take advantage of this flexibility, and States are not required to make any changes under this policy, we also believe the additional flexibility in plan and benefit design may produce long-term premium savings. The policies offer issuers in States that use the flexibility to select a new EHB-benchmark plan the opportunity to lower plan premiums, which will increase affordability of health insurance for consumers in the individual and small group markets who do not receive PTC and do not require the benefits that are no longer considered EHB.

When adjusting coverage of services under the options, we encourage States to consider the spillover effects in addition to the costs and utilization of these services. Spillover effects include increased use of other services, such as increased use of emergency services or increased use of public services provided by the State or other government entities, when a certain service is no longer covered by insurance. Depending on the State population's use of services and health care needs, States may arrive at different conclusions about the effects of adjusting a particular benefit. Because we do not know how States will choose to adjust their benchmark plans, we are not able to predict the effects these modifications may have on costs.

Additionally, we also proposed at § 156.115 to allow for benefit substitution to occur within the same EHB category or between EHB categories to offer additional issuer flexibility. Because issuers are already familiar with substituting benefits within benefit categories, we did not believe that broadening the policy to allow benefit substitution between benefit categories would create additional burden for issuers. We are finalizing § 156.115 to allow issuers to substitute benefits between EHB categories to the extent allowed by the State, beginning in plan year 2020. As finalized, this rule will increase burden on consumers, when their State allows between-category substitution and issuers in their State utilize such substitution. Under such circumstances, consumers who choose between plans offered in the individual and small group markets may need to spend more time and effort comparing benefits offered by different plans in order to determine what, if any, benefits are substituted, and what plan would best suit their health care and financial needs. However, some consumers may benefit from expanded access to plans that better suit their needs. We also note that States are generally primarily responsible for enforcement of EHB and continue to have the option to set criteria for benefit substitution.

We solicited comments on the impact of the proposed EHB policy and on whether other impacts should be considered.

Comment: Many commenters were concerned about the impact of the proposed EHB-benchmark plan policies. Some commenters were concerned that reduced benefits might lead to consumers forgoing care, which could lead to a more serious condition that would increase or shift costs. Some commenters focused on the potential downstream effects, with most commenters agreeing with our assessment that there may be potential downstream effects that a State would want to take under consideration, with some noting that the spillover could also affect the productivity of the nation, leading to even higher government costs.

Commenters on the premium impact and cost impact of the proposed policy typically were concerned that reducing benefits would only have a minor or no premium impact and would result in consumers having to pay more for services that are not covered, which some noted is not what consumers want. Some of these commenters noted that premiums are affected by other factors than benefits while some commenters were concerned about the risk pool impact and risk adjustment since enrollment could be affected by the scope of benefits being offered. Other commenters noted that Medicaid, the large group and self-insured plans, and PTC are also affected by the definition of EHB.

Commenters also opposed allowing issuers to substitute benefits between EHB categories. Commenters cited a wide range of concerns, including those we acknowledged in the proposed rule, as well as several that we did not, and suggested that the proposal's negative impact would be significant. For example, commenters noted that this type of substitution would permit issuers to design plans so that they were unattractive to people with certain high-cost health conditions, or people with conditions not adequately reimbursed by risk adjustment. They voiced concerns that this new market dynamic could harm the individual market risk pool and State risk adjustment programs, as well as imposing burden on certain individuals with chronic or high cost conditions affected by the lack of coverage options that met their needs and the difficulty of comparing plans due to the increased complexity of plan design.

Commenters also stated that substitution between EHB benefit categories is significantly different than substitution within categories and, therefore that current substitution practices do not provide helpful precedent for plan design, or for States' review of plans that include substitution within categories. One commenter stated that it would be particularly difficult to establish actuarial equivalence between benefits from different EHB-benefit categories, which could result in added burden for State regulators and for issuers required to comply with varying standards in different States. One commenter added that while this proposal would allow States to bar issuers from using benefit substitution between EHB categories, some States would need to take this step through legislative action, which would require time and resources simply to maintain their current policy. Finally, we did not receive any examples of how issuers could use substitution between EHB benefit categories to improve coverage options.

Response: In response to commenters, we are finalizing the new EHB-benchmark plan options at § 156.111 with certain modifications. Because we do not know how States will choose to adjust their benchmark plans, we are not able to predict the effects these modifications may have on costs. Furthermore, we also recognize that the effects of a specific change will likely vary from State to State given market and demographic differences. Therefore, we emphasize that States may also wish to consider a variety of different factors when selecting an EHB-benchmark plan. We encourage States to consider the impact of the EHB-benchmark plan's scope of benefits on the availability of PTC and CSRs for enrollees in the State, as the PTC is based on the amount of premiums allocable to EHB, and CSRs provide reduced cost sharing for EHB only. Additionally, we encourage States to consider the impact on Medicaid, and on large group and self-insured group health plans. While we cannot predict the effects of the policy, we hope that this policy, as finalized, allows States the flexibility to innovate their EHB-benchmark plans that balances access and costs. We hope to learn from those States that choose a new EHB-benchmark plan under this policy, as we consider creating a Federal default benchmark plan in the future.

We appreciate commenters' concerns about the impact of allowing substitution between EHB categories. We assess the impact on States to be minimal, as under the final rule they have authority to withhold permission for substitution between categories. We also expect minimal impact on issuers, since they have experience in substituting benefits within EHB categories and may decline to substitute between categories even when their State allows it.

We anticipate both additional burden and benefit for consumers, to the extent that their States permit and issuers utilize substitution between EHB categories. It may require greater time and effort for consumers to choose among plans in the individual and small group market if some of those plans substitute some benefits for those in separate EHB categories. However, we anticipate that this additional time and effort will be limited because issuers must meet the requirement at § 156.115(b)(3)(i) to provide benefits that are substantially equal to their State's EHB-benchmark plan. The impact on consumers of the substituted benefits themselves will be mixed—some consumers stand to benefit by gaining access to benefits they desire that would not have been provided without this policy, while other consumers may find that a particular issuer no longer offers benefits they desire. Benefits no longer offered by one issuer, however, may be offered by another issuer. The net effect is uncertain.

15. Application to Stand-Alone Dental Plans Inside the Exchange (§ 156.150)

We are removing AV level of coverage requirements for SADP issuers for coverage of pediatric dental EHB, however we are maintaining the AV certification requirement at revised § 156.150(b)(2) and codifying an operational requirement that such certification be reported to the Exchange, which issuers of SADPs have already been fulfilling, as part of the QHP certification process. We estimate that the change in AV could lead to a reduction in premiums for certain SADPs. Issuers may choose to offer more SADPs at varying premiums and levels of coverage. The offering of more SADPs and SADPs with lower premiums may lead to increased enrollment in SADPs. Because certain eligible taxpayers can use PTC to pay for the portion of SADP premiums attributable to EHB, a reduction in premiums will likely reduce the premium for purposes of the PTC, leading to a small transfer from credit recipients to the government. If enrollment increases due to potentially lower premiums there may be an overall increase in the total PTC payments by the government. The net effect is uncertain. While the requirement to report a SADP's AV is newly codified in regulation, issuers of SADPs previously reported level of coverage as part of the QHP certification process, so this change is not expected to have an impact on issuers' reporting burden.

16. Qualified Health Plan Certification

For plan years 2019 and later, we proposed to further expand the role of States in the QHP certification process for FFEs, including FFEs where the State performs plan management functions. Specifically, we proposed to defer to States for additional review areas, including accreditation requirements at § 156.275, compliance reviews at § 156.715, minimum geographic area of the plan's service area at § 155.1055, and quality improvement strategy reporting at § 156.1130, if feasible and appropriate. We received comments that this policy would impose burdens on States, particularly those States that are not performing these reviews, and we are not finalizing this proposal for these four review areas. Some States commented that they presently lack resources, including staffing resources, to conduct these reviews. We are finalizing a policy to extend for the 2019 benefit year and beyond the QHP certification review standards related to network adequacy and ECPs that we finalized in the Market Stabilization rule. We do not anticipate this policy will increase burden on States because we believe these reviews are already being performed by States. We anticipated slight reduction in burden for issuers due to not needing to undergo duplicative reviews and a reduction in costs to the Federal government. We sought comment on whether there are burdens we are not considering. While commenters expressed concern that these policies could increase burden for consumers to obtain care from needed providers, we believe that State reviews related to network adequacy are capable of adequately preserving consumer access to care from such providers.

We are removing the meaningful difference standard at § 156.298. Issuers will have a potential reduction in administrative costs since they will no longer have to implement their internal assessments as to whether their plan offerings meet this standard. We acknowledged and commenters noted that consumers may have more QHPs to select from which may increase the burden in selecting a QHP. However, we do not have evidence from any Exchange that removing the meaningful difference standard creates any new burden on consumers.

We also anticipate that the removal of the meaningful difference standard will reduce the regulatory burden on SBE–FPs. Under § 155.200(f)(2)(iv), SBE–FPs are required to establish and oversee requirements for their issuers that are no less stringent than the meaningful difference standard as it applies to issuers participating in the FFEs. SBE–FPs will no longer need to establish such a standard or oversee it.

We are removing the requirements for SBE–FPs to enforce FFE standards for network adequacy at § 155.200(f)(2)(ii) and essential community providers at § 155.200(f)(2)(iii). We anticipate that SBE–FPs will have a potential reduction in administrative costs since they will have the flexibility to determine how to implement the network adequacy and essential community provider standards with which issuers offering QHPs through the SBE–FP must comply. We believe SBE–FPs are best positioned to determine these standards for the QHP certification process in their States, and that the removal of the requirement that SBE–FPs establish and oversee requirements for their issuers that are no less strict that the manner in which these regulatory requirements are applied to FFE issuers will streamline certain aspects of the QHP certification process, reduce issuer burden, and return traditional insurance market regulatory authority to the States.

17. Provisions Related to Cost Sharing (§ 156.130)

The PPACA provides for the reduction or elimination of cost sharing for certain eligible individuals enrolled in QHPs offered through the Exchanges. This assistance helps many low- and moderate-income individuals and families obtain health insurance—for many people, cost sharing is a barrier to obtaining needed health care.[105]

We set forth in this final rule the reductions in the maximum annual limitation on cost sharing for silver plan variations. Consistent with our analysis in previous Payment Notices, we developed three model silver level QHPs and analyzed the impact on their AVs of the reductions described in the PPACA to the estimated 2019 maximum annual limitation on cost sharing for self-only coverage. We do not believe these changes will result in a significant economic impact. Therefore, we do not believe the provisions related to cost-sharing reductions in this final rule will have an impact on the program established by and described in past Payment Notices.

We also finalized the premium adjustment percentage for the 2019 benefit year. Under § 156.130(e), and under the methodology established in the 2015 Payment Notice and amended in the 2015 Market Standards Rule for estimating average per capita premium for purposes of calculating the premium adjustment percentage, the premium adjustment percentage is the percentage (if any) by which the average per enrollee premium for employer-sponsored health insurance coverage for the preceding calendar year exceeds such average per enrollee premium for employer-sponsored health insurance for 2013. The annual premium adjustment percentage sets the rate of increase for three parameters detailed in the PPACA: The annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code, and the assessable payments under sections 4980H(a) and 4980H(b) of the Code. We believe that the 2019 premium adjustment percentage is well within the parameters used in the modeling of the PPACA, and we do not expect that these provisions will alter CBO's March 2016 baseline estimates of the budget impact.

18. Minimum Essential Coverage (§ 156.602, § 156.604)

We proposed to designate CHIP buy-in programs that provide identical coverage to the CHIP program under title XXI of the Act in the applicable State as minimum essential coverage. This final rule does not provide categorical designation of CHIP buy-in programs as minimum essential coverage. States will have the option of electronically submitting to HHS information regarding their plans and, after review and comparison of the coverage, HHS will verify whether or not the CHIP buy-in programs provide at least the same coverage as the title XXI CHIP programs, such that they statutorily qualify as minimum essential coverage. Currently, very few States offer CHIP buy-in programs, and such plans in two States have applied for and been recognized as minimum essential coverage. Of the States that opt into the verification process, there will be a reduction in burden related to making changes to their plans to provide at least the same coverage as the title XXI CHIP program.

19. Medical Loss Ratio (Part 158)

We are amending § 158.221(b) to allow issuers the option to report a single quality improvement activity expense amount equal to 0.8 percent of earned premium, in lieu of reporting the actual QIA amounts in five separate categories described in § 158.150(b)(2)(i)–(v). Based on MLR data for the 2015 MLR reporting year, HHS estimates that the amendment will decrease rebate payments from issuers to consumers by approximately $23 million.

We are also amending several sections of 45 CFR part 158, subpart C (§§ 158.301, 158.321–158.322, 158.330, 158.341, 158.350) to modify the process and criteria for the Secretary to determine whether to adjust the 80 percent MLR standard in the individual market in a State. While it is uncertain what specific adjustments States may request, most adjustments previously granted by the Secretary have ranged from 70 to 75 percent. Based on MLR data for the 2015 MLR reporting year, and assuming that 22 States will request an adjustment (including 17 States that previously requested adjustments prior to 2014), HHS estimates that the amendments will decrease rebate payments from issuers to consumers or increase premiums paid by consumers to issuers by approximately $52 million (assuming a reduction of the 80 percent MLR standard to 75 percent for all 22 States) to $64 million (assuming a reduction of the MLR standard to 70 percent for all 22 States) annually, for up to 3 years at a time. This represents an estimated 74 percent to 91 percent reduction, respectively, in rebates payable in those 22 States, which together accounted for $70 million out of the nationwide total $107 million in rebates that issuers owed to individual market consumers for 2015. The actual reduction in rebates may be lower or higher depending on which States apply for an adjustment, and whether and how much the Secretary may adjust the individual market MLR standard in each State.

20. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the proposed rule will be the number of reviewers of this final rule. We acknowledge that this

[105] Brook, Robert H., John E. Ware, William H. Rogers, Emmett B. Keeler, Allyson Ross Davies, Cathy D. Sherbourne, George A. Goldberg, Kathleen N. Lohr, Patricia Camp and Joseph P. Newhouse. *The Effect of Coinsurance on the Health of Adults: Results from the RAND Health Insurance Experiment.* Santa Monica, CA: RAND Corporation, 1984. Available at *http://www.rand.org/pubs/reports/R3055*.

assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule.

We are required to promulgate a substantial portion of this rule each year under our regulations and we estimate that approximately half of the remaining provisions will cause additional regulatory review burden that stakeholders do not already anticipate. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule, excluding the portion of the rule that we are required to promulgate each year.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits.[106] Assuming an average reading speed, we estimate that it will take approximately 1 hour for the staff to review the relevant portions of this proposed rule that causes unanticipated burden. We received 416 comments, including 99 comments that were substantially similar to one of four different letters, resulting in 322 unique comments on the proposed rule. We assume that for form letters, only the staff at the organization that arranged for those letters will review the final rule. For each entity that reviews the rule, the estimated cost is $105.16. Therefore, we estimate that the total cost of reviewing this regulation is approximately $33,862 ($105.16 × 322 reviewers). This may underestimate the review costs, since not all reviewers may have submitted comments. In addition, stakeholders that will need to do a detailed analysis in order to implement the unanticipated provisions of this rule will need additional time and personnel, which will vary depending on the extent to which they are affected. To estimate an upper bound, we assumed that on average 530 issuers and 50 States will spend 10 hours each, 100 other organizations will spend 5 hours each and 100 individuals will spend 1 hour each to review the rule. Under these assumptions, total time spent reviewing the rule would be 6,400 hours with an estimated cost of approximately $673,024.

D. Regulatory Alternatives Considered

In developing the policies contained in the final rule, we considered numerous alternatives to the policies being finalized. Below, we discuss the key regulatory alternatives that we considered.

For the 2019 benefit year, we considered using only the 2016 benefit year enrollee-level EDGE data to recalibrate the risk adjustment model coefficients. However, this could lead to uncertainty in issuers' expectation of risk adjustment transfers due to the sole use of a new dataset for recalibrating the model coefficients. We believe that blending multiple years of data will promote stability for the risk adjustment coefficients year-to-year, particularly for rare conditions with small sample sizes. Therefore, we proposed to blend coefficients calculated from the 2016 benefit year enrollee-level EDGE data with 2014 and 2015 MarketScan® data. Additionally, given the timing of the proposed rule, we were unable to analyze the 2016 enrollee-level EDGE data in time to publish the coefficients calibrated using the EDGE data in the proposed rule. Similar to the 2018 benefit year final risk adjustment coefficients, we considered publishing the 2019 benefit year final risk adjustment coefficients in guidance after the publication of the final rule with more recent MarketScan® data that will become available at the end of this year. However, the 2016 benefit year enrollee-level risk adjustment data was available in time to complete our analysis and publish the final coefficients in this rule. Additionally, we considered but did not propose to use the 2016 MarketScan® data that will become available at the end of this year for the 2019 benefit year risk adjustment model recalibration. We also considered assigning higher weights to the coefficients solved from more recent data, however, to allow stability in the market have equally blended the 3 years of data. We are finalizing the 2019 benefit year model coefficients blended with 2016 EDGE data, and 2014 and 2015 MarketScan® data published in this rule.

For the State flexibility to request reductions of other applicable risk adjustment transfers, we considered alternate requirements for States requesting a reduction. We considered requiring actuarially certified standards, State's attestation noting consensus from all issuers of risk adjustment covered plans in the State's market, or simulation studies demonstrating the effect of the reduction on State's market risk pool. We determined that to ensure issuers are adequately compensated for the actuarial risk of their enrollees and do not have incentives to avoid higher risk enrollees, the State regulators need to submit evidence and analysis demonstrating the State-specific factors that warrant an adjustment to more precisely account for the differences in actuarial risk in the State's market. States must also justify the percentage reduction by providing evidence and analysis demonstrating the State-specific factors and the percentage by which those factors warrant an adjustment to more precisely account for the differences in actuarial risk in the State's market as compared to the national norm, or demonstrating the requested reduction in risk adjustment payments would be so small for issuers who would receive risk adjustment payments, that the reduction would have a *de minimis* effect on the necessary premium increase to cover the affected issuer's or issuers' reduced payments. We also considered only making the flexibility available to States in the small group market, but determined that just as with the States' small group markets, it is possible that the national methodology may not precisely account for unique State market dynamics in the individual or merged markets.

For the risk adjustment data validation program, HHS considered alternate approaches for evaluating error rates and adjusting risk scores when an error rate deviates from a statistically significant value. We considered calculating a national central tendency of errors and then adjusting risk scores only when an error rate that falls outside of the confidence interval around the national central tendency; however, we determined that the evaluation of error rates relative to a national average would likely result in significantly less accurate risk score adjustments, primarily because it would not account for differences in error rates due to issuer size or the distribution of HCCs in the enrollee population.

We considered maintaining the current applicability of the Federal rate review requirements, and continuing to review the reasonableness of student health insurance coverage rate increases subject to review. However, this rule will provide States with greater flexibility to meet the needs of their markets and reduce the burden associated with review of plans that are not part of the single risk pool. As a practical matter, student health insurance coverage has generally been given the same plan design flexibility as

[106] *https://www.bls.gov/oes/current/oes_nat.htm.*

plans in the large group market. Just like purchasers of large group plans, purchasers in the student market are viewed as more sophisticated, with greater leverage and ability to avoid the imposition of unreasonable rate increases. Single risk pool pricing, the primary focus of the rate review program, does not apply to student health insurance coverage.

We considered maintaining the current 30-day notice requirement for States to notify HHS prior to posting the required information on proposed and final rate increases. However, such advanced notice may be impractical in some States so we have decreased the notice requirement to 5 business days. We considered permitting States to post the required information on rate increases on a rolling basis. However, we agree with the concerns shared by the majority of public comments opposing that proposal, so we are maintaining the uniform posting requirement.

In adding standards for § 155.221, HHS considered making no changes to the existing rule and retaining the existing standard for agents and brokers to contract with a third-party entity approved by HHS for conducting audits under the section. In finalizing the proposal, we continue to believe that it is necessary to include issuers and to provide the necessary flexibility in oversight that both protects consumers and encourages enrollment pathway innovation for agents, brokers, and issuers using direct enrollment.

For the amendments to § 155.320, we considered developing a comprehensive database using information from employers on the plans they offer to their employees and their family members that could satisfy verification requirements under paragraph (d)(2) for all Exchanges. This approach would be resource-intensive for Exchanges, and would produce a database with limited utility due to data limitations. Developing a database; recruiting and educating employers to participate in voluntarily submitting the data; and providing technical assistance to employers for the first year of implementation on how to input the data is estimated to cost at least $38 million. Building such a database would also rely on the voluntary participation of substantially all employers. This participation would be onerous for employers. Employers would need to provide individual employee level data regarding plans the employer will offer, information that may not be available in time to populate a comprehensive database prior to the Exchange's plan year. In addition, since the PPACA does not require employers to provide to the Exchange the relevant information on what coverage they offer, Exchanges and HHS would not receive data from all employers. After weighing our options, we decided that this approach would be overly costly and burdensome, and of limited value due to gaps in the data Exchanges and HHS would be able to collect. We also considered removing the requirement to connect to an HHS-approved data source, and the requirement to use an alternative method if the Exchange does not connect to the required data sources, but were concerned about the potential impact on program integrity.

In finalizing the policy related to the SHOP enrollment process, we considered maintaining the status quo, but believe that the increase in flexibility, cost savings and reduction in burden resulting from the new enrollment approach, will have a positive impact on small businesses across the country and provide States with needed flexibility.

In finalizing the policy for the new EHB-benchmark plan selection options described at § 156.111, we considered a variety of alternatives, including maintaining the current EHB-benchmark policy without modification. Although maintaining the current policy would have promoted stability by preserving the current EHB-benchmarks across all States, we do not believe it would have offered the additional flexibility that States have requested in selecting an EHB-benchmark plan to best meet the needs of their consumer population. We also considered whether it was feasible to offer States increased flexibility by allowing them to set a range of acceptable EHB within their State, such that issuers could offer plans within that range with more limited EHB coverage or more robust EHB coverage. However, we determined that this option did not meet statutory requirements. To balance stability, flexibility, and statutory requirements, we instead finalized the proposal to offer States the expanded EHB-benchmark plan selection options at § 156.111, as well as the option to default to the State's current EHB-benchmark plan. We believe this approach will provide States with the opportunity to take advantage of greater flexibility in selecting an EHB-benchmark plan while also providing those States that value stability with the option to retain their current benchmark plan.

With respect to the provision regarding removing the AV requirement for SADPs, we considered making no change or proposing an expansion to the de minimis range to mirror the expanded de minimis range for QHPs (−4/+2 percentage points) or of +/−3 percentage points. We determined that these alternatives were less desirable because they do not provide issuers with as much flexibility to offer a range of SADPs as the proposed removal of the AV standards for SADPs. We finalized the policy to remove the level of coverage AV requirement for SADPs as proposed, but retained a requirement to certify AV and codified an operational requirement that such certification be reported to the Exchange, which SADP issuers already have been doing, as part of the QHP certification process. For the QHP certification standard regarding meaningful difference, we considered maintaining the requirement on issuers, but we believe that removing this provision will promote the offering of a variety of affordable QHPs that will meet consumers' needs, will provide issuers with more flexibility, and will remove an unnecessary regulatory requirement.

For the amendments to § 158.221(b), we considered retaining the current quality improvement activity reporting requirements, since giving issuers the option to report a standardized rate for QIA expenditures may inhibit HHS from being able to analyze trends in issuers' investment in improving the quality of health care in the future, and may also reduce rebates to consumers by allowing issuers to effectively increase their MLRs by 0.8 percent even if those issuers engaged in and spent only trivial amounts on QIA. However, this change will also potentially level the playing field among issuers to a certain extent and lead to more accurate rebate payments, since many issuers likely do engage in QIA but forego reporting that spending because the burden of analyzing, documenting, tracking, allocating, and reporting QIA expenses exceeds the benefits for MLR purposes. Because the finalized approach of giving issuers the option to report a minimal, standardized rate will reduce unwarranted regulatory and economic burdens for issuers that do not want to track and report the exact QIA amounts for their MLR calculation, we believe that the finalized approach will be more effective and represents a better balance than the current requirements.

For the amendments to part 158, subpart C, we considered retaining the current requirements for States to request an adjustment to the 80 percent MLR standard in the individual market in a State. However, HHS recognizes that many of the current State application requirements are burdensome and less relevant in the

post-2014 reformed environment, and may preclude or discourage States from proposing innovative solutions to help stabilize their individual markets. Therefore, we believe the finalized amendments will reduce regulatory burdens on States, and provide States with an additional tool to promote stability in their individual markets.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

This final rule includes standards for the risk adjustment and risk adjustment data validation programs, which are intended to stabilize premiums as insurance market reforms are implemented and Exchanges facilitate increased enrollment. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for ''small entities'' established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

For purposes of the RFA, we expect the following types of entities to be affected by this final rule:

- Health insurance issuers.
- Group health plans.

We believe that health insurance issuers and group health plans will be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $38.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers may possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $32.5 million or less.[107] We believe that few, if any, insurance companies selling comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds.

This final rule will allow enrollment in a SHOP QHP through a SHOP-registered agent or broker, or through a participating QHP issuer. The SHOPs are generally limited by statute to employers with at least one but not more than 50 employees, unless a State opts to provide that employers with from 1 to 100 employees are ''small employers.'' For this reason, we expect that many employers who will be affected by the finalized policies will meet the SBA standard for small entities. We do not believe that the finalized policies impose requirements on employers offering health insurance through a SHOP that are more restrictive than the current requirements on small businesses offering employer sponsored insurance. We believe the processes that we have established constitute the minimum amount of requirements necessary to implement the SHOP program and accomplish our policy goals, and that no appropriate regulatory alternatives can be developed to further lessen the compliance burden.

Based on data from MLR annual report submissions for the 2015 MLR reporting year, approximately 92 out of over 530 issuers of health insurance coverage nationwide had total premium revenue of $38.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since almost 50 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that would result in their revenues exceeding $38.5 million. We estimate that 57 of these 92 potentially small entities may experience a decrease in the rebate amount owed to consumers under the amendments to the quality improvement activity reporting provisions in part 158, and 27 of these 57 entities are part of larger holding groups. In addition, we estimate that no small entities will be impacted by the amendments to 45 CFR part 158, subpart C. Therefore, we believe that the provisions of this final rule regarding MLR will not affect a substantial number of small entities, and further, the impact of the proposed QIA provisions on small entities will be positive.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any 1 year by a State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $148 million. Although we have not been able to quantify all costs, we expect the combined impact on State, local, or Tribal governments and the private sector to be below the threshold.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, HHS has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

While developing this rule, HHS attempted to balance the States' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, it is HHS's view that we have complied with the requirements of Executive Order 13132.

Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For States that elected previously to operate an Exchange, or risk adjustment program, much of the initial cost of creating these programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the

[107] ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes'', effective February 26, 2016, U.S. Small Business Administration, available at *https://www.sba.gov/contracting/getting-started-contractor/make-sure-you-meet-sba-size-standards/table-smallbusiness-size-standards.*

State. Current State Exchanges charge user fees to issuers.

In HHS's view, while this final rule will not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. For example, we are finalizing proposals to provide States with substantially more flexibility in selecting an EHB-benchmark plan, to explore ways to make it easier for States to establish and maintain a State Exchange, to provide States with substantially more flexibility in how they operate a SHOP, to provide States with the option to request a reduction to risk adjustment transfers in their small group market; and to make it easier for States to apply for and be granted an adjustment to the MLR standard in their State. We are also returning flexibility to States in their review of rate increases. We are also finalizing the proposal to give States the choice to review rate increases for student health insurance coverage. We are also reducing the advanced notification that States must give HHS about the posting of rate increases from 30 days to 5 business days. Finally, States will no longer be required to seek approval if the State-specific threshold for reasonableness review is lower than the Federal default rate review threshold.

H. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to Congress and the Comptroller for review.

I. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise promulgates, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. This final rule is an E.O. 13771 deregulatory action.[108]

List of Subjects

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Intergovernmental relations, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 154

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grants administration, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Conflict of interests, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

45 CFR Part 157

Employee benefit plans, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 147, 153, 154, 155, 156, 157 and 158 as set forth below.

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 1. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 2. Section 147.102 is amended by revising paragraph (c)(3)(iii)((D) to read as follows:

§ 147.102 Fair health insurance premiums.

* * * * *

(c) * * *

(3) * * *

(iii) * * *

(D) To the extent permitted by applicable State law and, in the case of coverage offered through a SHOP, as permitted by the SHOP, apply this paragraph (c)(3)(iii) uniformly among group health plans enrolling in that product, giving those group health plans the option to pay premiums based on average enrollee premium amounts.

* * * * *

■ 3. Section 147.104 is amended by—

■ a. Revising paragraphs (b)(1)(i)(B), (b)(1)(i)(C) and (b)(1)(ii);

■ b. Removing paragraph (b)(1)(iii); and

■ c. Revising paragraphs (b)(2)(i) introductory text and (ii).

The revisions read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(b) * * *

(1) * * *

(i) * * *

[108] We estimate cost savings of approximately $52.74 million in 2018, $58.12 million in 2019, and annual cost savings of $4.12 million thereafter. Thus the annualized value of cost savings, as of 2016 and calculated over a perpetual time horizon with a 7 percent discount rate, is $9.26 million.

(B) In the case of a group health plan in the small group market that cannot comply with employer contribution or group participation rules for the offering of health insurance coverage, as allowed under applicable State law, and in the case of a QHP offered in the SHOP, as permitted by § 156.285(e) or § 156.286(e) of this subchapter, a health insurance issuer may restrict the availability of coverage to an annual enrollment period that begins November 15 and extends through December 15 of each calendar year.

(C) With respect to coverage in the small group market, and in the large group market if such coverage is offered through a SHOP in a State, for a group enrollment received on the first through the fifteenth day of any month, the coverage effective date must be no later than the first day of the following month. For a group enrollment received on the 16th through last day of any month, the coverage effective date must be no later than the first day of the second following month. In either such case, a small employer may instead opt for a later effective date within a quarter for which small group market rates are available.

(ii) *Individual market.* A health insurance issuer in the individual market must allow an individual to purchase health insurance coverage during the initial and annual open enrollment periods described in § 155.410(b) and (e) of this subchapter. Coverage must become effective consistent with the dates described in § 155.410(c) and (f) of this subchapter.

(2) * * *

(i) A health insurance issuer in the individual market must provide a limited open enrollment period for the triggering events described in § 155.420(d) of this subchapter, excluding, with respect to coverage offered outside of an Exchange, the following:

* * * * *

(ii) In applying this paragraph (b)(2), a reference in § 155.420 (other than in § 155.420(a)(5)) of this subchapter to a ''QHP'' is deemed to refer to a plan, a reference to ''the Exchange'' is deemed to refer to the applicable State authority, and a reference to a ''qualified individual'' is deemed to refer to an individual in the individual market.

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 4. The authority citation for part 153 continues to read as follows:

Authority: Secs. 1311, 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

■ 5. Section 153.320 is amended by adding paragraph (d) to read as follows:

§ 153.320 Federally certified risk adjustment methodology.

* * * * *

(d) *State flexibility to request reductions to transfers.* Beginning with the 2020 benefit year, States can request to reduce risk adjustment transfers in the State's individual, small group or merged markets by up to 50 percent in States where HHS operates the risk adjustment program.

(1) *State requests.* State requests for a reduction to transfers must include:

(i) Supporting evidence and analysis demonstrating the State-specific factors that warrant an adjustment to more precisely account for the differences in actuarial risk in the State market;

(ii) The adjustment percentage of up to 50 percent requested for the State individual, small group or merged market; and

(iii) A justification for the reduction requested demonstrating the State-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State individual, small group or merged market, or demonstrating the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(2) *Timeframe to Submit Reduction Requests.* States must submit requests for a reduction to transfer in the individual, small group or merged market by August 1 of the year, 2 calendar years prior to the applicable benefit year in the form and manner specified by HHS.

(3) *Publication of Reduction Requests.* HHS will publish State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters proposed rule and make the supporting evidence available to the public for comment. HHS will publish any approved State reduction requests or denied State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters final rule.

(4) *HHS approval.* (i) Subject to paragraph (d)(4)(ii) of this section, HHS will approve State requests if HHS determines, based on the review of the information submitted as part of the State's request, along with other relevant factors, including the premium impact of the transfer reduction for the State market, and relevant public comments:

(A) That State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State individual, small group or merged market and support the percentage reduction to risk adjustment transfers requested; or

(B) That State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual, small group or merged market and the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(ii) HHS may approve a reduction amount that is lower than the amount requested by the State if the supporting evidence and analysis do not fully support the requested reduction amount. HHS will assess other relevant factors, including the premium impact of the transfer reduction for the State market.

■ 6. Section 153.630 is amended by revising paragraphs (b)(6), (8), and (9) to read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * * *

(b) * * *

(6) An issuer must provide the initial validation auditor and the second validation auditor with all relevant source enrollment documentation, all claims and encounter data, and medical record documentation from providers of services to each enrollee in the applicable sample without unreasonable delay and in a manner that reasonably assures confidentiality and security in transmission. Notwithstanding any other provision of this section, a qualified provider that is licensed to diagnose mental illness by the State and that is prohibited from furnishing a complete medical record by applicable State privacy laws concerning any enrollee's treatment for one or more mental or behavioral health conditions may furnish a signed mental or behavioral health assessment that, to the extent permissible under applicable Federal and State privacy laws, should contain: The enrollee's name; sex; date of birth; current status of all mental or behavioral health diagnoses; and dates of service. The mental or behavioral health assessment should be signed by the provider and submitted with an attestation that the provider is prohibited from furnishing a complete medical record by applicable State privacy laws.

* * * * *

(8) The initial validation auditor must measure and report to the issuer and HHS, in a manner and timeframe specified by HHS, its inter-rater reliability rates among its reviewers. The initial validation auditor must achieve a consistency measure of at least 95 percent for his or her review outcomes, except that for validation of risk adjustment data for the 2015 and 2016 benefit years, the initial validation auditor may meet an inter-rater reliability standard of 85 percent for review outcomes.

(9) HHS may impose civil money penalties in accordance with the procedures set forth in § 156.805(b) through (e) of this subchapter if an issuer of a risk adjustment covered plan—

(i) Fails to engage an initial validation auditor;

(ii) Fails to submit the results of an initial validation audit to HHS;

(iii) Engages in misconduct or substantial non-compliance with the risk adjustment data validation standards and requirements applicable to issuers of risk adjustment covered plans; or

(iv) Intentionally or recklessly misrepresents or falsifies information that it furnishes to HHS.

* * * * *

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

■ 7. The authority citation for part 154 continues to read as follows:

Authority: Section 2794 of the Public Health Service Act (42 U.S.C. 300gg–94).

■ 8. Section 154.103 is amended by revising paragraph (b) to read as follows:

§ 154.103 Applicability.

* * * * *

(b) *Exceptions.* The requirements of this part do not apply to—

(1) Grandfathered health plan coverage as defined in § 147.140 of this subchapter;

(2) Excepted benefits as described in section 2791(c) of the PHS Act; and

(3) For coverage effective on or after July 1, 2018, student health insurance coverage as defined in § 147.145 of this subchapter.

■ 9. Section 154.200 is revised to read as follows:

§ 154.200 Rate increases subject to review.

(a) A rate increase filed in a State, or effective in a State that does not require a rate increase to be filed, is subject to review if:

(1) The rate increase is 15 percent or more applicable to a 12-month period that begins on January 1, as calculated under paragraph (b) of this section; or

(2) The rate increase meets or exceeds a State-specific threshold applicable to a 12-month period that begins on January 1, as calculated under paragraph (b) of this section, determined by the Secretary. A State-specific threshold shall be based on factors impacting rate increases in a State to the extent that the data relating to such State-specific factors are available by August 1 of the preceding year. States interested in proposing a State-specific threshold greater than the Federal default stated in paragraph (a)(1) of this section are required to submit a proposal for approval of such threshold to the Secretary by August 1 of the preceding year, in the form and manner specified by the Secretary.

(b) A rate increase meets or exceeds the applicable threshold set forth in paragraph (a) of this section if the average increase, including premium rating factors described in § 147.102 of this subchapter, for all enrollees weighted by premium volume for any plan within the product meets or exceeds the applicable threshold.

(c) If a rate increase that does not otherwise meet or exceed the threshold under paragraph (b) of this section meets or exceeds the threshold when combined with a previous increase or increases during the 12-month period preceding the date on which the rate increase would become effective, then the rate increase must be considered to meet or exceed the threshold and is subject to review under § 154.210, and such review shall include a review of the aggregate rate increases during the applicable 12-month period.

■ 10. Section 154.215 is amended by revising paragraph (h)(2) to read as follows:

§ 154.215 Submission of rate filing justification.

* * * * *

(h) * * *

(2) CMS will make available to the public on its website the information contained in Parts I and III of each Rate Filing Justification that is not a trade secret or confidential commercial or financial information as defined in HHS's Freedom of Information Act regulations, 45 CFR 5.31(d).

* * * * *

■ 11. Section 154.301 is amended by revising paragraph (b)(2) to read as follows:

§ 154.301 CMS's determinations of Effective Rate Review Programs.

* * * * *

(b) * * *

(2) If a State intends to make the information in paragraph (b)(1)(i) of this section available to the public prior to the date specified by the Secretary, or if it intends to make the information in paragraph (b)(1)(ii) of this section available to the public prior to the first day of the annual open enrollment period in the individual market for the applicable calendar year, the State must notify CMS in writing, no later than five (5) business days prior to the date it intends to make the information public, of its intent to do so and the date it intends to make the information public.

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

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

Authority: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1332, 1334, 1402, 1411, 1412, 1413, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083).

■ 13. Section 155.106 is amended by revising paragraph (c) introductory text to read as follows:

§ 155.106 Election to operate an Exchange after 2014.

* * * * *

(c) *Process for State Exchanges that seek to utilize the Federal platform for select functions.* States may seek approval to operate a State Exchange utilizing the Federal platform for only the individual market. A State seeking approval to operate a State Exchange utilizing the Federal platform for the individual market to support select functions through a Federal platform agreement under § 155.200(f) must:

* * * * *

■ 14. Section 155.200 is amended by removing and reserving paragraphs (f)(2)(ii) through (iv); and revising paragraph (f)(4) introductory text to read as follows;

§ 155.200 Functions of an Exchange.

* * * * *

(f) * * *

(2) * * *

(ii) [Reserved]

(iii) [Reserved]

(iv) [Reserved]

* * * * *

(4) A State Exchange on the Federal platform that utilizes the Federal

platform for SHOP functions, for plan years beginning on or after January 1, 2018, must require its QHP issuers to make any changes to rates in accordance with the timeline applicable in a Federally-facilitated SHOP under § 155.706(b)(6)(i)(A). A State Exchange on the Federal platform that utilizes the Federal platform for SHOP functions, as set forth in paragraphs (f)(4)(i) through (vii) of this section, for plan years beginning prior to January 1, 2018, must—

* * * * *

■ 15. Section 155.210 is amended by revising paragraphs (c)(2) introductory text and (e)(7) to read as follows:

§ 155.210 Navigator program standards.

* * * * *

(c) * * *

(2) The Exchange must include an entity from at least one of the following categories for receipt of a Navigator grant:

* * * * *

(e) * * *

(7) In a Federally-facilitated Exchange, no individual or entity shall be ineligible to operate as a Navigator solely because its principal place of business is outside of the Exchange service area;

* * * * *

■ 16. Section 155.215 is amended by revising paragraph (h) to read as follows:

§ 155.215 Standards applicable to Navigators and Non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210 in a Federally-facilitated Exchange and to Non-Navigator Assistance Personnel funded through an Exchange Establishment Grant.

* * * * *

(h) *Physical presence.* In a Federally-facilitated Exchange, no individual or entity shall be ineligible to operate as a non-Navigator entity or as non-Navigator assistance personnel solely because its principal place of business is outside of the Exchange service area.

* * * * *

■ 17. Section 155.221 is revised to read as follows:

§ 155.221 Standards for third-parties to perform audits of agents, brokers, and issuers participating in direct enrollment.

(a) An agent, broker, or issuer participating in direct enrollment must engage a third-party entity to conduct an annual review to demonstrate operational readiness in accordance with § 155.220(c)(3)(i)(K) and with § 156.1230(b)(2) of this subchapter. The third-party entity will be a downstream or delegated entity of the agent, broker or issuer that participates or wishes to participate in direct enrollment.

(b) An agent, broker, or issuer participating in direct enrollment must satisfy the requirement to demonstrate operational readiness under paragraph (a) of this section by engaging a third-party entity that meets each of the following standards:

(1) Has experience conducting audits or similar services, including experience with relevant privacy and security standards;

(2) Adheres to HHS specifications for content, format, privacy, and security in the conduct of an operational readiness review, which includes ensuring that agents, brokers, and issuers are in compliance with the applicable privacy and security standards and other applicable requirements;

(3) Collects, stores, and shares with HHS all data related to the third-party entity's audit of agents, brokers, and issuers in a manner, format, and frequency specified by HHS until 10 years from the date of creation, and complies with the privacy and security standards HHS adopts for agents, brokers, and issuers as required in accordance with § 155.260;

(4) Discloses to HHS any financial relationships between the entity and individuals who own or are employed by an agent, broker, or issuer for which it is conducting an operational readiness review.

(5) Complies with all applicable Federal and State requirements;

(6) Ensures, on an annual basis, that appropriate staff successfully complete operational readiness review training as established by HHS prior to conducting audits under paragraph (a) of this section;

(7) Permits access by the Secretary and the Office of the Inspector General or their designees in connection with their right to evaluate through audit, inspection, or other means, to the third-party entity's books, contracts, computers, or other electronic systems, relating to the third-party entity's audits of agent's, broker's, or issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the date of creation; and

(8) Complies with other minimum business criteria as specified in guidance by HHS.

(c) An agent, broker or issuer may engage multiple third-party entities to conduct the audit under paragraph (a) of this section and each third-party entity must satisfy the standards outlined under paragraph (b) of this section.

■ 18. Section 155.305 is amended by revising paragraph (f)(4) to read as follows:

§ 155.305 Eligibility standards.

* * * * *

(f) * * *

(4) *Compliance with filing requirement.* The Exchange may not determine a tax filer eligible for APTC if HHS notifies the Exchange as part of the process described in § 155.320(c)(3) that APTC were made on behalf of the tax filer or either spouse if the tax filer is a married couple for a year for which tax data would be utilized for verification of household income and family size in accordance with § 155.320(c)(1)(i), and the tax filer or his or her spouse did not comply with the requirement to file an income tax return for that year as required by 26 U.S.C. 6011, 6012, and implementing regulations and reconcile the advance payments of the premium tax credit for that period.

* * * * *

■ 19. Section 155.320 is amended by—

■ a. Revising paragraphs (c)(3)(iii) introductory text, and paragraph (c)(3)(iii)(A);

■ b. Adding paragraphs (c)(3)(iii)(D) through (F);

■ c. Revising paragraph (c)(3)(vi)(C), (D), (F) and (G); and

■ d. Revising paragraph (d)(4) introductory text.

The revisions and additions read as follows:

§ 155.320 Verification process related to eligibility for insurance affordability programs.

* * * * *

(c) * * *

(3) * * *

(iii) *Verification process for changes in household income.* (A) Except as specified in paragraph (c)(3)(iii)(B), (C), and (D) of this section, if an applicant's attestation, in accordance with paragraph (c)(3)(ii)(B) of this section, indicates that a tax filer's annual household income has increased or is reasonably expected to increase from the data described in paragraph (c)(3)(ii)(A) of this section for the benefit year for which the applicant(s) in the tax filer's family are requesting coverage and the Exchange has not verified the applicant's MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGI-based income standard, the Exchange must accept the applicant's attestation regarding a tax filer's annual household income without further verification.

* * * * *

(D) If an applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is greater than or equal to 100 percent but not more than 400 percent of the FPL for the benefit year for which coverage is requested and is more than a reasonable threshold above the annual household income computed in accordance with paragraph (c)(3)(ii)(A) of this section, the data described in paragraph (c)(3)(ii)(A) of this section indicates that projected annual household income is under 100 percent FPL, and the Exchange has not verified the applicant's MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGI-based income standard, the Exchange must proceed in accordance with § 155.315(f)(1) through (4). However, this paragraph (c)(3)(iii)(D) does not apply if the applicant is a non-citizen who is lawfully present and ineligible for Medicaid by reason of immigration status. For the purposes of this paragraph, a reasonable threshold is established by the Exchange in guidance and approved by HHS, but must not be less than 10 percent, and can also include a threshold dollar amount.

(E) If, at the conclusion of the period specified in § 155.315(f)(2)(ii), the Exchange remains unable to verify the applicant's attestation, the Exchange must determine the applicant's eligibility based on the information described in paragraph (c)(3)(ii)(A) of this section, notify the applicant of such determination in accordance with the notice requirements specified in § 155.310(g), and implement such determination in accordance with the effective dates specified in § 155.330(f).

(F) If, at the conclusion of the period specified in § 155.315(f)(2)(ii), the Exchange remains unable to verify the applicant's attestation and the information described in paragraph (c)(3)(ii)(A) of this section is unavailable, the Exchange must determine the tax filer ineligible for advance payments of the premium tax credit and cost-sharing reductions, notify the applicant of such determination in accordance with the notice requirements specified in § 155.310(g), and discontinue any advance payments of the premium tax credit and cost-sharing reductions in accordance with the effective dates specified in § 155.330(f).

* * * * *

(vi) * * *

(C) *Increases in annual household income.* If an applicant's attestation, in accordance with paragraph (c)(3)(ii)(B) of this section, indicates that a tax filer's annual household income has increased or is reasonably expected to increase from the data described in paragraph (c)(3)(vi)(A) of this section to the benefit year for which the applicant(s) in the tax filer's family are requesting coverage and the Exchange has not verified the applicant's MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGI-based income standard, the Exchange must accept the applicant's attestation for the tax filer's family without further verification, unless:

(*1*) The Exchange finds that an applicant's attestation of a tax filer's annual household income is not reasonably compatible with other information provided by the application filer, or

(*2*) The data described in paragraph (c)(3)(vi)(A) of this section indicates that projected annual household income is under 100 percent FPL and the applicant's attestation to projected household income, as described in paragraph (c)(3)(ii)(B) of this section, is greater than or equal to 100 percent but not more than 400 percent of the FPL for the benefit year for which coverage is requested and is more than a reasonable threshold above the annual household income as computed using data sources described in paragraph (c)(3)(vi)(A) of this section, in which case the Exchange must follow the procedures specified in § 155.315(f)(1) through (4). The reasonable threshold used under this paragraph must be equal to the reasonable threshold established in accordance with paragraph (c)(3)(iii)(D) of this section.

(D) *Decreases in annual household income and situations in which electronic data is unavailable.* If electronic data are unavailable or an applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is more than a reasonable threshold below the annual household income as computed using data sources described in paragraphs (c)(3)(vi)(A) of this section, the Exchange must follow the procedures specified in § 155.315(f)(1) through (4). The reasonable threshold used under this paragraph must be equal to the reasonable threshold established in accordance with paragraph (c)(3)(vi) of this section.

* * * * *

(F) If, at the conclusion of the period specified in § 155.315(f)(2)(ii), the Exchange remains unable to verify the applicant's attestation, the Exchange must determine the applicant's eligibility based on the information described in paragraph (c)(3)(ii)(A) of this section, notify the applicant of such determination in accordance with the notice requirements specified in § 155.310(g), and implement such determination in accordance with the effective dates specified in § 155.330(f).

(G) If, at the conclusion of the period specified in § 155.315(f)(2)(ii), the Exchange remains unable to verify the applicant's attestation for the tax filer and the information described in paragraph (c)(3)(ii)(A) of this section is unavailable, the Exchange must determine the tax filer ineligible for advance payments of the premium tax credit and cost-sharing reductions, notify the applicant of such determination in accordance with the notice requirement specified in § 155.310(g), and discontinue any advance payments of the premium tax credit and cost-sharing reductions in accordance with the effective dates specified in § 155.330(f).

* * * * *

(d) * * *

(4) *Alternate procedures.* For any benefit year for which it does not reasonably expect to obtain sufficient verification data as described in paragraphs (d)(2)(i) through (iii) of this section, the Exchange must follow the procedures specified in paragraph (d)(4)(i) of this section or, for benefit years 2016 through 2019, the Exchange may follow the procedures specified in paragraph (d)(4)(ii) of this section. For purposes of this paragraph (d)(4), the Exchange reasonably expects to obtain sufficient verification data for any benefit year when, for the benefit year, the Exchange is able to obtain data about enrollment in and eligibility for qualifying coverage in an eligible employer-sponsored plan from at least one electronic data source that is available to the Exchange and that has been approved by HHS, based on evidence showing that the data source is sufficiently current, accurate, and minimizes administrative burden, as described under paragraph (d)(2)(i) of this section.

* * * * *

■ 20. Section 155.420 is amended by:
■ a. Revising paragraphs (a)(4)(iii), (a)(5) and (b)(2)(i);
■ b. Removing paragraph (b)(2)(v);
■ c. Redesignating paragraph (b)(2)(vi) as paragraph (b)(2)(v);
■ d. Revising paragraph (d)(1)(iii); and
■ e. Revising paragraph (d)(10)(i).

The revisions read as follows:

§ 155.420 Special enrollment periods.

(a) * * *

(4) * * *

(iii) For the other triggering events specified in paragraph (d) of this section, except for paragraphs (d)(2)(i), (d)(4), (d)(6)(i) and (ii) of this section for becoming newly eligible for CSRs, (d)(8), (9), (10) and (12) of this section:

(A) If an enrollee qualifies for a special enrollment period, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b) of this subchapter; or

(B) If a dependent qualifies for a special enrollment period, and an enrollee is adding the dependent to his or her QHP, the Exchange must allow the enrollee to add the dependent to his or her current QHP; or, if the QHP's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b) of this subchapter, or enroll the new qualified individual in a separate QHP.

(5) *Prior coverage requirement.* Qualified individuals who are required to demonstrate coverage in the 60 days prior to a qualifying event can either demonstrate that they had minimum essential coverage as described in 26 CFR 1.5000A–1(b) for 1 or more days during the 60 days preceding the date of the qualifying event; lived in a foreign country or in a United States territory for 1 or more days during the 60 days preceding the date of the qualifying event; are an Indian as defined by section 4 of the Indian Health Care Improvement Act; or lived for 1 or more days during the 60 days preceding the qualifying event or during their most recent preceding enrollment period, as specified in §§ 155.410 and 155.420, in a service area where no qualified health plan was available through the Exchange.

(b) * * *

(2) * * *

(i) In the case of birth, adoption, placement for adoption, placement in foster care, or child support or other court order as described in paragraph (d)(2)(i) of this section, the Exchange must ensure that coverage is effective for a qualified individual or enrollee on the date of birth, adoption, placement for adoption, placement in foster care, or effective date of court order; or it may permit the qualified individual or enrollee to elect a coverage effective date of the first of the month following plan selection; or in accordance with paragraph (b)(1) of this section. If the Exchange permits the qualified individual or enrollee to elect a coverage effective date of either the first of the month following the date of plan selection or in accordance with paragraph (b)(1) of this section, the Exchange must ensure coverage is effective on the date duly selected by the qualified individual or enrollee.

* * * * *

(d) * * *

(1) * * *

(iii) Loses pregnancy-related coverage described under section 1902(a)(10)(A)(i)(IV) and (a)(10)(A)(ii)(IX) of the Act (42 U.S.C. 1396a(a)(10)(A)(i)(IV), (a)(10)(A)(ii)(IX)) or loses access to health care services through coverage provided to a pregnant woman's unborn child, based on the definition of a child in 42 CFR 457.10. The date of the loss of coverage is the last day the qualified individual would have pregnancy-related coverage or access to health care services through the unborn child coverage; or

* * * * *

(10) * * *

(i) Is a victim of domestic abuse or spousal abandonment as defined by 26 CFR 1.36B–2 or a dependent or unmarried victim within a household, is enrolled in minimum essential coverage, and sought to enroll in coverage separate from the perpetrator of the abuse or abandonment; or

* * * * *

■ 21. Section 155.430 is amended by:

■ a. Revising paragraph (d)(2)(ii);

■ b. Redesignating paragraphs (d)(2)(iii), (d)(2)(iv) and (d)(2)(v) as paragraphs (d)(2)(iv), (d)(2)(v), and (d)(2)(vi), respectively;

■ c. Adding new paragraph (d)(2)(iii); and

■ d. Revising newly redesignated paragraphs (d)(2)(iv), and (v).

The revisions and additions read as follows:

§ 155.430 Termination of Exchange enrollment or coverage.

* * * * *

(d) * * *

(2) * * *

(ii) If the enrollee does not provide reasonable notice, fourteen days after the termination is requested by the enrollee; or

(iii) At the option of the Exchange, on the date on which the termination is requested by the enrollee, or on another prospective date selected by the enrollee; or

(iv) If an Exchange does not require an earlier termination date in accordance with paragraph (d)(2)(iii) of this section, at the option of the QHP issuer, on a date on or after the termination is requested by the enrollee that is less than 14 days after the termination is requested by the enrollee, if the enrollee requests an earlier termination date; or

(v) At the option of the Exchange, for an individual who is newly determined eligible for Medicaid, CHIP, or the Basic Health Program, if a Basic Health Program is operating in the service area of the Exchange, the day before the enrollee's date of eligibility for Medicaid, CHIP, or the Basic Health Program.

* * * * *

■ 22. Section 155.500 is amended by revising the definitions of ''Appeal request'' and ''Appeals entity'' to read as follows:

§ 155.500 Definitions.

* * * * *

Appeal request means a clear expression, either orally or in writing, by an applicant, enrollee, employer, or small business employer or employee to have any eligibility determination or redetermination contained in a notice issued in accordance with § 155.310(g), § 155.330(e)(1)(ii), § 155.335(h)(1)(ii), § 155.610(i), § 155.715(e) or (f), or § 155.716(e) reviewed by an appeals entity.

Appeals entity means a body designated to hear appeals of eligibility determinations or redeterminations contained in notices issued in accordance with § 155.310(g), § 155.330(e)(1)(ii), § 155.335(h)(1)(ii), § 155.610(i), § 155.715(e) and (f), or § 155.716(e).

* * * * *

■ 23. Section 155.605 is amended by revising paragraph (d)(2)(iv) to read as follows:

§ 155.605 Eligibility standards for exemptions.

* * * * *

(d) * * *

(2) * * *

(iv) For an individual who is ineligible to purchase coverage under an eligible employer-sponsored plan, the Exchange determines the required contribution for coverage in accordance with section 5000A(e)(1)(B)(ii) of the Code, inclusive of all members of the family, as defined in 26 CFR 1.36B–1(d), who have not otherwise been granted an exemption through the Exchange and who are not treated as eligible to purchase coverage under an eligible employer-sponsored plan, in accordance with paragraph (d)(4)(ii) of this section. If there is not a bronze level plan offered through the Exchange in the

individual's county, the Exchange must use the annual premium for the lowest cost Exchange metal level plan, excluding catastrophic coverage, available in the individual market through the Exchange in the State in the county in which the individual resides to determine whether coverage exceeds the affordability threshold specified in section 5000A(e)(1) of the Code; and

* * * * *

■ 24. Section 155.610 is amended by revising paragraph (h)(2) to read as follows:

§ 155.610 Eligibility process for exemptions.

* * * * *

(h) * * *

(2) The Exchange will only accept an application for an exemption described in § 155.605(d)(1) during one of the 3 calendar years after the month or months during which the applicant attests that the hardship occurred.

* * * * *

■ 25. Section 155.700 is amended by revising paragraph (a) to read as follows:

§ 155.700 Standards for the establishment of a SHOP.

(a) *General requirement.* (1) For plan years beginning before January 1, 2018, an Exchange must provide for the establishment of a SHOP that meets the requirements of this subpart and is designed to assist qualified employers and facilitate the enrollment of qualified employees into qualified health plans.

(2) For plan years beginning on or after January 1, 2018, an Exchange must provide for the establishment of a SHOP that meets the requirements of this subpart and is designed to assist qualified employers in facilitating the enrollment of their employees in qualified health plans.

* * * * *

■ 26. Section 155.705 is amended by revising the section heading and adding paragraph (e) to read as follows:

§ 155.705 Functions of a SHOP for plan years beginning prior to January 1, 2018.

* * * * *

(e) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.706 is applicable for plan years beginning on or after January 1, 2018.

■ 27. Section 155.706 is added to read as follows:

§ 155.706 Functions of a SHOP for plan years beginning on or after January 1, 2018.

(a) *Exchange functions that apply to SHOP.* The SHOP must carry out all the required functions of an Exchange described in this subpart and in subparts C, E, K, and M of this part, except:

(1) Requirements related to individual eligibility determinations in subpart D of this part;

(2) Requirements related to enrollment of qualified individuals described in subpart E of this part;

(3) The requirement to issue certificates of exemption in accordance with § 155.200(b); and

(4) Requirements related to the payment of premiums by individuals, Indian tribes, tribal organizations and urban Indian organizations under § 155.240.

(b) *Unique functions of a SHOP.* The SHOP must also provide the following unique functions:

(1) *Enrollment and eligibility functions.* The SHOP must adhere to the requirements outlined in subpart H.

(2) *Employer choice requirements.* The SHOP must allow a qualified employer to select a level of coverage as described in section 1302(d)(1) of the Affordable Care Act, in which all QHPs within that level are made available to the qualified employees of the employer.

(3) *SHOP options with respect to employer choice requirements.* (i) A SHOP:

(A) Must allow an employer to make available to qualified employees all QHPs at the level of coverage selected by the employer as described in paragraph (b)(2) of this section, and

(B) May allow an employer to make one or more QHPs available to qualified employees by a method other than the method described in paragraph (b)(2) of this section.

(ii) A Federally-facilitated SHOP will provide a qualified employer a choice of two methods to make QHPs available to qualified employees:

(A) The employer may choose a level of coverage as described in paragraph (b)(2) of this section, or

(B) The employer may choose a single QHP.

(iii) A SHOP may, and a Federally-facilitated SHOP will provide a qualified employer a choice of two methods to make stand-alone dental plans available to qualified employees:

(A) The employer may choose to make available a single stand-alone dental plan.

(B) The employer may choose to make available all stand-alone dental plans offered through a SHOP.

(iv) A SHOP may also provide a qualified employer with a choice of a third method to make QHPs available to qualified employees by offering its qualified employees a choice of all QHPs offered through the SHOP by a single issuer across all available levels of coverage, as described in section 1302(d)(1) of the Affordable Care Act and implemented in § 156.140(b) of this subchapter. A State with a Federally-facilitated SHOP may recommend that the Federally-facilitated SHOP not make this additional option available in that State, by submitting a letter to HHS in advance of the annual QHP certification application deadline, by a date to be established by HHS. The State's letter must describe and justify the State's recommendation, based on the anticipated impact this additional option would have on the small group market and consumers.

(v) A SHOP may also provide a qualified employer with a choice of a third method to make stand-alone dental plans available to qualified employees by offering its qualified employees a choice of all stand-alone dental plans offered through the SHOP by a single issuer. A State with a Federally-facilitated SHOP may recommend that the Federally-facilitated SHOP not make this additional option available in that State, by submitting a letter to HHS in advance of the annual QHP certification application deadline, by a date to be established by HHS. The State's letter must describe and justify the State's recommendation, based on the anticipated impact this additional option would have on the small group market and consumers.

(vi) States operating a State Exchange utilizing the Federal platform for SHOP enrollment functions will have the same employer choice models available as States with a Federally-facilitated SHOP, except that a State with a State Exchange utilizing the Federal platform for SHOP enrollment functions may decide against offering the employer choice models specified in paragraphs (b)(3)(iv) and (v) of this section in that State, provided that the State notifies HHS of that decision in advance of the annual QHP certification application deadline, by a date to be established by HHS.

(4) *Continuation of Coverage.* The SHOP may, upon an election by a qualified employer, enter into an agreement with a qualified employer to facilitate the administration of continuation coverage by collecting premiums for continuation coverage enrolled in through the SHOP directly from a person enrolled in continuation coverage through the SHOP consistent with applicable law and the terms of the group health plan, and remitting

premium payments for this coverage to QHP issuers.

(5) *QHP Certification.* With respect to certification of QHPs in the small group market, the SHOP must ensure each QHP meets the requirements specified in § 156.285 of this subchapter.

(6) *Rates and rate changes.* The SHOP must—

(i) Require all QHP issuers to make any change to rates at a uniform time that is no more frequently than quarterly.

(A) In a Federally-facilitated SHOP, rates may be updated quarterly with effective dates of January 1, April 1, July 1, or October 1 of each calendar year. The updated rates must be submitted to HHS at least 60 days in advance of the effective date of the rates.

(B) [Reserved]

(ii) Prohibit all QHP issuers from varying rates for a qualified employer during the employer's plan year.

(7) *QHP availability in merged markets.* If a State merges the individual market and the small group market risk pools in accordance with section 1312(c)(3) of the Affordable Care Act, the SHOP may permit employer groups to enroll in any QHP meeting level of coverage requirements described in section 1302(d) of the Affordable Care Act.

(8) *QHP availability in unmerged markets.* If a State does not merge the individual and small group market risk pools, the SHOP must permit employer groups to enroll only in QHPs in the small group market.

(9) *SHOP expansion to large group market.* If a State elects to expand the SHOP to the large group market, a SHOP must allow issuers of health insurance coverage in the large group market in the State to offer QHPs in such market through a SHOP beginning in 2017 provided that a large employer meets the qualified employer requirements other than that it be a small employer.

(10) *Participation rules.* Subject to § 147.104 of this subchapter, the SHOP may authorize a uniform group participation rate for the offering of health insurance coverage in the SHOP, which must be a single, uniform rate that applies to all groups and issuers in the SHOP. If the SHOP authorizes a minimum participation rate, such rate must be based on the rate of employee participation in the SHOP, not on the rate of employee participation in any particular QHP or QHPs of any particular issuer.

(i) Subject to § 147.104 of this subchapter, a Federally-facilitated SHOP must use a minimum participation rate of 70 percent, calculated as the number of full-time employees accepting coverage offered by a qualified employer plus the number of full-time employees who, at the time the employer submits the SHOP group enrollment, are enrolled in coverage through another group health plan, governmental coverage (such as Medicare, Medicaid, or TRICARE), coverage sold through the individual market, or in other minimum essential coverage, divided by the number of full-time employees offered coverage.

(ii) Notwithstanding paragraphs (b)(10)(i) of this section, a Federally-facilitated SHOP may utilize a different minimum participation rate in a State if there is evidence that a State law sets a minimum participation rate or that a higher or lower minimum participation rate is customarily used by the majority of QHP issuers in that State for products in the State's small group market outside the SHOP.

(11) *Premium calculator.* In the SHOP, the premium calculator described in § 155.205(b)(6) must facilitate the comparison of available QHPs.

(c) *Coordination with individual market Exchange for eligibility determinations.* A SHOP that collects employee eligibility or enrollment data must provide data related to eligibility and enrollment of a qualified employee to the individual market Exchange that corresponds to the service area of the SHOP, unless the SHOP is operated pursuant to § 155.100(a)(2).

(d) *Duties of Navigators in the SHOP.* In States that have elected to operate only a SHOP pursuant to § 155.100(a)(2), at State option and if State law permits the Navigator duties described in § 155.210(e)(3) and (4) may be fulfilled through referrals to agents and brokers.

(e) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

■ 28. Section 155.715 is amended by revising the section heading and adding paragraph (h) to read as follows:

§ 155.715 Eligibility determination process for SHOP for plan years beginning prior to January 1, 2018.

* * * * *

(h) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.716 is applicable for plan years beginning on or after January 1, 2018.

■ 29. Section 155.716 is added to read as follows:

§ 155.716 Eligibility determination process for SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirement.* The SHOP must determine whether an employer requesting a determination of eligibility to participate in a SHOP is eligible in accordance with the requirements of § 155.710.

(b) *Applications.* The SHOP must accept a SHOP single employer application form from employers, in accordance with the relevant standards of § 155.730.

(c) *Verification of eligibility.* For the purpose of verifying employer eligibility, the SHOP—

(1) May establish, in addition to or in lieu of reliance on the application, additional methods to verify the information provided by the applicant on the applicable application;

(2) Must collect only the minimum information necessary for verification of eligibility in accordance with the eligibility standards described in § 155.710; and

(3) May not perform individual market Exchange eligibility determinations or verifications described in subpart D of this part.

(d) *Eligibility adjustment period.* When the information submitted on the SHOP single employer application is inconsistent with information collected from third-party data sources through the verification process described in paragraph (c)(1) of this section or otherwise received by the SHOP, the SHOP must—

(1) Make a reasonable effort to identify and address the causes of such inconsistency, including through typographical or other clerical errors;

(2) Notify the employer of the inconsistency;

(3) Provide the employer with a period of 30 days from the date on which the notice described in paragraph (d)(2) of this section is sent to the employer to either present satisfactory documentary evidence to support the employer's application, or resolve the inconsistency; and

(4) If, after the 30-day period described in paragraph (d)(2) of this section, the SHOP has not received satisfactory documentary evidence, the SHOP must—

(i) Notify the employer of its denial or termination of eligibility in accordance with paragraph (e) of this section and of the employer's right to appeal such determination; and

(ii) If the employer was enrolled pending the confirmation or verification of eligibility information, discontinue the employer's participation in the

SHOP at the end of the month following the month in which the notice is sent.

(e) *Notification of employer eligibility.* The SHOP must provide an employer requesting eligibility to purchase coverage through the SHOP with a notice of approval or denial or termination of eligibility and the employer's right to appeal such eligibility determination.

(f) *Validity of Eligibility Determination.* An employer's determination of eligibility to participate in SHOP remains valid until the employer makes a change that could end its eligibility under § 155.710(b) or withdraws from participation in the SHOP.

(g) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

■ 30. Section 155.720 is amended by revising the section heading and adding paragraph (j) to read as follows:

§ 155.720 Enrollment of employees into QHPs under SHOP for plan years beginning prior to January 1, 2018.

* * * * *

(j) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.721 is applicable for plan years beginning on or after January 1, 2018.

■ 31. Section 155.721 is added to read as follows:

§ 155.721 Record retention and IRS Reporting for plan years beginning on or after January 1, 2018.

(a) *Records.* The SHOP must receive and maintain for at least 10 years records of qualified employers participating in the SHOP.

(b) *Reporting requirement for tax administration purposes.* The SHOP must, at the request of the IRS, report information to the IRS about employer eligibility to participate in SHOP coverage.

(c) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

■ 32. Section 155.725 is amended by revising the section heading and adding paragraph (l) to read as follows:

§ 155.725 Enrollment periods under SHOP for plan years beginning prior to January 1, 2018.

* * * * *

(l) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.726 is applicable for plan years beginning on or after January 1, 2018.

■ 33. Section 155.726 is added to read as follows:

§ 155.726 Enrollment periods under SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirements.* The SHOP must ensure that issuers offering QHPs through the SHOP adhere to applicable enrollment periods, including special enrollment periods.

(b) *Rolling enrollment in the SHOP.* The SHOP must permit a qualified employer to purchase coverage for its small group at any point during the year. The employer's plan year must consist of the 12-month period beginning with the qualified employer's effective date of coverage, unless the plan is issued in a State that has elected to merge its individual and small group risk pools under section 1312(c)(3) of the Affordable Care Act, in which case the plan year will end on December 31 of the calendar year in which coverage first became effective.

(c) *Special enrollment periods.* (1) The SHOP must ensure that issuers offering QHPs through the SHOP provide special enrollment periods consistent with the section, during which certain qualified employees or dependents of qualified employees may enroll in QHPs and enrollees may change QHPs.

(2) The SHOP must ensure that issuers offering QHPs through a SHOP provide a special enrollment period for a qualified employee or a dependent of a qualified employee who;

(i) Experiences an event described in § 155.420(d)(1) (other than paragraph (d)(1)(ii)), or experiences an event described in § 155.420(d)(2), (4), (5), (7), (8), (9), (10), (11), or (12);

(ii) Loses eligibility for coverage under a Medicaid plan under title XIX of the Social Security Act or a State child health plan under title XXI of the Social Security Act; or

(iii) Becomes eligible for assistance, with respect to coverage under a SHOP, under such Medicaid plan or a State child health plan (including any waiver or demonstration project conducted under or in relation to such a plan).

(3) A qualified employee or dependent of a qualified employee who experiences a qualifying event described in paragraph (j)(2) of this section has:

(i) Thirty (30) days from the date of a triggering event described in paragraph (c)(2)(i) of this section to select a QHP through the SHOP; and

(ii) Sixty (60) days from the date of a triggering event described in paragraph (c)(2)(ii) or (iii) of this section to select a QHP through the SHOP;

(4) A dependent of a qualified employee is not eligible for a special enrollment period if the employer does not extend the offer of coverage to dependents.

(5) The effective dates of coverage for special enrollment periods are determined using the provisions of § 155.420(b).

(6) Loss of minimum essential coverage is determined using the provisions of § 155.420(e).

(d) *Limitation.* Qualified employees will not be able to enroll unless the employer group meets any applicable minimum participation rate implemented under § 155.706(b)(10).

(e) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

■ 34. Section 155.730 is amended by revising the section heading and adding paragraph (h) to read as follows:

§ 155.730 Application standards for SHOP for plan year beginning prior to January 1, 2018.

* * * * *

(h) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.731 is applicable for plan years beginning on or after January 1, 2018.

■ 35. Section 155.731 is added to read as follows:

§ 155.731 Application standards for SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirements.* Application forms used by the SHOP must meet the requirements set forth in this section.

(b) *Single employer application.* The SHOP must use a single application to determine employer eligibility. Such application must collect the following—

(1) Employer name and address of employer's locations;

(2) Information sufficient to confirm the employer is a small employer;

(3) Employer Identification Number (EIN); and

(4) Information sufficient to confirm that the employer is offering, at a minimum, all full-time employees coverage in a QHP through a SHOP.

(c) *Model application.* The SHOP may use the model single employer application provided by HHS.

(d) *Alternative employer application.* The SHOP may use an alternative application if such application is approved by HHS and collects the information described in paragraph (b).

(e) *Filing.* The SHOP must:

(1) Accept applications from SHOP application filers; and

(2) Provide the tools to file an employer eligibility application via an internet website.

(f) *Additional safeguards.* (1) The SHOP may not provide to the employer any information collected on an

employee application with respect to spouses or dependents other than the name, address, and birth date of the spouse or dependent.

(2) The SHOP is not permitted to collect information on the single employer or on an employee application unless that information is necessary to determine SHOP eligibility or effectuate enrollment through the SHOP.

(g) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

■ 36. Section 155.735 is amended by revising the section heading and adding paragraph (h) to read as follows:

§ 155.735 Termination of SHOP enrollment or coverage for plan years beginning prior to January 1, 2018.

* * * * *

(h) *Applicability date.* The provisions of this section apply for plan years beginning before January 1, 2018.

■ 37. Section 155.740 is amended by revising the section heading and adding paragraph (p) to read as follows:

§ 155.740 SHOP employer and employee eligibility appeals requirements for plan years beginning prior to January 1, 2018.

* * * * *

(p) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.741 is applicable for plan years beginning on or after January 1, 2018.

■ 38. Section 155.741 is added to subpart H to read as follows:

§ 155.741 SHOP employer and employee eligibility appeals requirements for plan year beginning on or after January 1, 2018.

(a) *Definitions.* The definitions in §§ 155.20, 155.300, and 155.500 apply to this section.

(b) *General requirements.* (1) A State, establishing an Exchange that provides for the establishment of a SHOP pursuant to § 155.100 must provide an eligibility appeals process for the SHOP. Where a State has not established an Exchange that provides for the establishment of a SHOP pursuant to § 155.100, HHS will provide an eligibility appeals process for the SHOP that meets the requirements of this section and the requirements in paragraph (b)(2) of this section.

(2) The appeals entity must conduct appeals in accordance with the requirements established in this section and §§ 155.505(e) through (h) and 155.510(a)(1) and (2) and (c).

(c) *Employer right to appeal.* An employer may appeal—

(1) A notice of denial or termination of eligibility under § 155.716(e); or

(2) A failure by the SHOP to provide a timely eligibility determination or a timely notice of an eligibility determination in accordance with § 155.716(e).

(d) *Appeals notice requirement.* Notices of the right to appeal a denial of eligibility under § 155.716(e) must be written and include—

(1) The reason for the denial or termination of eligibility, including a citation to the applicable regulations; and

(2) The procedure by which the employer may request an appeal of the denial or termination of eligibility.

(e) *Appeal request.* The SHOP and appeals entity must—

(1) Allow an employer to request an appeal within 90 days from the date of the notice of denial or termination of eligibility to—

(i) The SHOP or the appeals entity; or

(ii) HHS, if no State Exchange that provides for establishment of a SHOP has been established;

(2) Accept appeal requests submitted through any of the methods described in § 155.520(a)(1);

(3) Comply with the requirements of § 155.520(a)(2) and (3); and

(4) Consider an appeal request valid if it is submitted in accordance with paragraph (e)(1) of this section.

(f) *Notice of appeal request.* (1) Upon receipt of a valid appeal request, the appeals entity must—

(i) Send timely acknowledgement to the employer of the receipt of the appeal request, including—

(A) An explanation of the appeals process; and

(B) Instructions for submitting additional evidence for consideration by the appeals entity.

(ii) Promptly notify the SHOP of the appeal, if the appeal request was not initially made to the SHOP.

(2) Upon receipt of an appeal request that is not valid because it fails to meet the requirements of this section, the appeals entity must—

(i) Promptly and without undue delay, send written notice to the employer that is appealing that—

(A) The appeal request has not been accepted,

(B) The nature of the defect in the appeal request; and

(C) An explanation that the employer may cure the defect and resubmit the appeal request if it meets the timeliness requirements of paragraph (e) of this section, or within a reasonable timeframe established by the appeals entity.

(ii) Treat as valid an amended appeal request that meets the requirements of this section.

(g) *Transmittal and receipt of records.* (1) Upon receipt of a valid appeal request under this section, or upon receipt of the notice under paragraph (f)(2) of this section, the SHOP must promptly transmit, via secure electronic interface, to the appeals entity—

(i) The appeal request, if the appeal request was initially made to the SHOP; and

(ii) The eligibility record of the employer that is appealing.

(2) The appeals entity must promptly confirm receipt of records transmitted pursuant to paragraph (g)(1) of this section to the SHOP that transmitted the records.

(h) *Dismissal of appeal.* The appeals entity—

(1) Must dismiss an appeal if the employer that is appealing—

(i) Withdraws the request in accordance with the standards set forth in § 155.530(a)(1); or

(ii) Fails to submit an appeal request meeting the standards specified in paragraph (e) of this section.

(2) Must provide timely notice to the employer that is appealing of the dismissal of the appeal request, including the reason for dismissal, and must notify the SHOP of the dismissal.

(3) May vacate a dismissal if the employer makes a written request within 30 days of the date of the notice of dismissal showing good cause why the dismissal should be vacated.

(i) *Procedural rights of the employer.* The appeals entity must provide the employer the opportunity to submit relevant evidence for review of the eligibility determination.

(j) *Adjudication of SHOP appeals.* SHOP appeals must—

(1) Comply with the standards set forth in § 155.555(i)(1) and (3); and

(2) Consider the information used to determine the employer's eligibility as well as any additional relevant evidence submitted during the course of the appeal by the employer or employee.

(k) *Appeal decisions.* Appeal decisions must—

(1) Be based solely on—

(i) The evidence referenced in paragraph (j)(2) of this section;

(ii) The eligibility requirements for the SHOP under § 155.710(b), as applicable.

(2) Comply with the standards set forth in § 155.545(a)(2) through (5)

(3) Be effective as follows:

(i) If an employer is found eligible under the decision, then at the employer's option, the effective date of coverage or enrollment through the SHOP under the decision can either be made retroactive to the effective date of coverage or enrollment through the

SHOP that the employer would have had if the employer had been correctly determined eligible, or prospective to the first day of the month following the date of the notice of the appeal decision.

(ii) If the employer is found ineligible under the decision, then the appeal decision is effective as of the date of the notice of the appeal decision.

(l) *Notice of appeal decision.* The appeals entity must issue written notice of the appeal decision to the employer and to the SHOP within 90 days of the date the appeal request is received.

(m) *Implementation of SHOP appeal decisions.* The SHOP must promptly implement the appeal decision upon receiving the notice under paragraph (l) of this section.

(n) *Appeal record.* Subject to the requirements of § 155.550, the appeal record must be accessible to the employer in a convenient format and at a convenient time.

(o) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 39. The authority citation for part 156 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1313, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 40. Section 156.100 is amended by revising the section heading and the introductory text and by adding paragraph (d) to read as follows:

§ 156.100 State selection of benchmark plan for plan years beginning prior to January 1, 2020.

For plan years beginning before January 1, 2020, each State may identify a base-benchmark plan according to the selection criteria described below:

* * * * *

(d) *Applicability date:* For plan years beginning on or after January 1, 2020, § 156.111 applies in place of this section.

■ 41. Section 156.111 is added to Subpart B to read as follows:

§ 156.111 State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020.

(a) Subject to paragraphs (b), (c), (d) and (e) of this section, for plan years beginning on or after January 1, 2020, a State may change its EHB-benchmark plan by:

(1) Selecting the EHB-benchmark plan that another State used for the 2017 plan year under § 156.100 and § 156.110;

(2) Replacing one or more categories of EHBs established at § 156.110(a) in the State's EHB-benchmark plan used for the 2017 plan year with the same category or categories of EHB from the EHB-benchmark plan that another State used for the 2017 plan year under § 156.100 and § 156.110; or

(3) Otherwise selecting a set of benefits that would become the State's EHB-benchmark plan.

(b) A State's EHB-benchmark plan must:

(1) *EHB coverage.* Provide coverage of items and services for at least the categories of benefits at § 156.110(a), including an appropriate balance of coverage for these categories of benefits.

(2) *Scope of benefits.* (i) Provide a scope of benefits equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, defined as either:

(A) One of the selecting State's 10 base-benchmark plan options established at § 156.100, and available for the selecting State's selection for the 2017 plan year; or

(B) The largest health insurance plan by enrollment within one of the five largest large group health insurance products by enrollment in the State, as product and plan are defined at § 144.103 of this subchapter, provided that:

(*1*) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products in the State;

(*2*) The plan provides minimum value, as defined under § 156.145;

(*3*) The benefits are not excepted benefits, as established under § 146.145(b), and § 148.220 of this subchapter; and

(*4*) The benefits in the plan are from a plan year beginning after December 31, 2013.

(ii) Not exceed the generosity of the most generous among a set of comparison plans, including:

(A) The State's EHB-benchmark plan used for the 2017 plan year, and

(B) Any of the State's base-benchmark plan options for the 2017 plan year described in § 156.100(a)(1), supplemented as necessary under § 156.110.

(iii) Not have benefits unduly weighted towards any of the categories of benefits at § 156.110(a);

(iv) Provide benefits for diverse segments of the population, including women, children, persons with disabilities, and other groups; and

(v) Not include discriminatory benefit designs that contravene the non-discrimination standards defined in § 156.125.

(c) The State must provide reasonable public notice and an opportunity for public comment on the State's selection of an EHB-benchmark plan that includes posting a notice on its opportunity for public comment with associated information on a relevant State website.

(d) A State must notify HHS of the selection of a new EHB-benchmark plan by a date to be determined by HHS for each applicable plan year.

(1) If the State does not make a selection by the annual selection date, or its benchmark plan selection does not meet the requirements of this section and section 1302 of the PPACA, the State's EHB-benchmark plan for the applicable plan year will be that State's EHB-benchmark plan applicable for the prior year.

(2) [Reserved]

(e) A State changing its EHB-benchmark plan under this section must submit documents in a format and manner specified by HHS by a date determined by HHS. These must include:

(1) A document confirming that the State's EHB-benchmark plan definition complies with the requirements under paragraphs (a), (b) and (c) of this section, including information on which selection option under paragraph (a) of this section the State is using, and whether the State is using another State's EHB-benchmark plan;

(2) An actuarial certification and an associated actuarial report from an actuary, who is a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies, that affirms:

(i) That the State's EHB-benchmark plan provides a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, as defined at (b)(2)(i) of this section; and

(ii) That the State's EHB-benchmark plan does not exceed the generosity of the most generous among the plans listed in paragraphs (b)(2)(ii)(A) and (B) of this section.

(3) The State's EHB-benchmark plan document that reflects the benefits and limitations, including medical management requirements, a schedule of benefits and, if the State is selecting its EHB-benchmark plan using the

option in paragraph (a)(3) of this section, a formulary drug list in a format and manner specified by HHS; and

(4) Other documentation specified by HHS, which is necessary to operationalize the State's EHB-benchmark plan.

■ 42. Section 156.115 is amended by revising paragraph (b) to read as follows:

§ 156.115 Provision of EHB.

* * * * *

(b) An issuer of a plan offering EHB may substitute benefits for those provided in the EHB-benchmark plan under the following conditions—

(1) The issuer substitutes a benefit that:

(i) Is actuarially equivalent to the benefit that is being replaced as determined in paragraph (b)(4) of this section; and

(ii) Is not a prescription drug benefit.

(2) An issuer may substitute a benefit under this paragraph:

(i) Within the same EHB category, unless prohibited by applicable State requirements; and

(ii) For plan years beginning on or after January 1, 2020, between EHB categories, if the State in which the plan will be offered has notified HHS that substitution between EHB categories is permitted in the State.

(3) The plan that includes substituted benefits must:

(i) Continue to comply with the requirements of paragraph (a) of this section, including by providing benefits that are substantially equal to the EHB-benchmark plan;

(ii) Provide an appropriate balance among the EHB categories such that benefits are not unduly weighted toward any category; and

(iii) Provide benefits for diverse segments of the population.

(4) The issuer submits to the State evidence of actuarial equivalence that is:

(i) Certified by a member of the American Academy of Actuaries;

(ii) Based on an analysis performed in accordance with generally accepted actuarial principles and methodologies;

(iii) Based on a standardized plan population; and

(iv) Determined without taking cost-sharing into account.

* * * * *

■ 43. Section 156.150 is amended by revising paragraph (b) to read as follows:

§ 156.150 Application to stand-alone dental plans inside the Exchange.

* * * * *

(b) *Calculation of AV.* A stand-alone dental plan:

(1) May not use the AV calculator in § 156.135; and

(2) Must have the plan's actuarial value of coverage for pediatric dental essential health benefits certified by a member of the American Academy of Actuaries using generally accepted actuarial principles and reported to the Exchange.

* * * * *

■ 44. Section 156.200 is amended by revising paragraph (b)(2) to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(b) * * *

(2) Comply with Exchange processes, procedures, and requirements set forth in accordance with subpart K of part 155 of this subchapter and, in the small group market, §§ 155.705 and 155.706 of this subchapter;

* * * * *

■ 45. Section 156.285 is amended by revising the section heading and adding paragraph (f) to read as follows:

§ 156.285 Additional standards specific to SHOP for plan years beginning prior to January 1, 2018.

* * * * *

(f) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Additional standards specific to SHOP for plan years beginning on or after January 1, 2018 are in § 156.286.

■ 46. Section 156.286 is added to read as follows:

§ 156.286 Additional standards specific to SHOP for plan years beginning on or after January 1, 2018.

(a) *SHOP rating and premium payment requirements.* QHP issuers offering a QHP through a SHOP must:

(1) Accept payment from a qualified employer or an enrollee, or a SHOP on behalf of a qualified employer or enrollee, in accordance with applicable SHOP requirements.

(2) Adhere to the SHOP timeline for rate setting as established in § 155.706(b)(6) of this subchapter;

(3) Charge the same contract rate for a plan year; and

(4) Adhere to the premium rating standards described in § 147.102 of this subchapter regardless of whether the QHP being sold through the SHOP is sold in the small group market or the large group market.

(b) *Enrollment periods and processes for the SHOP.* QHP issuers offering a QHP through the SHOP must adhere to enrollment periods and processes established by the SHOP, consistent with § 155.726 of this subchapter, and establish a uniform enrollment timeline and process for enrolling qualified employers and employer group members.

(c) *Enrollment process for the SHOP.* A QHP issuer offering a QHP through the SHOP must:

(1) Provide new enrollees with the enrollment information package as described in § 156.265(e); and

(2) Enroll all qualified employees consistent with the plan year of the applicable qualified employer.

(d) *Participation rules.* QHP issuers offering a QHP through the SHOP may impose group participation rules for the offering of health insurance coverage in connection with a QHP only if and to the extent authorized by the SHOP in accordance with § 155.706 of this subchapter.

(e) *Employer choice.* QHP issuers offering a QHP through the SHOP must accept enrollments from groups in accordance with the employer choice policies applicable to the SHOP under § 155.706(b)(3) of this subchapter.

(f) *Identification of SHOP enrollments.* QHP issuers offering a QHP through the SHOP must use a uniform enrollment form, maintain processes sufficient to identify whether a group market enrollment is an enrollment through the SHOP, and maintain records of SHOP enrollments for a period of 10 years following the enrollment.

(g) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

§ 156.298 [Removed]

■ 47. Section 156.298 is removed.

■ 48. Section 156.340 is amended by revising paragraph (a)(2) to read as follows:

§ 156.340 Standards for downstream and delegated entities.

(a) * * *

(2) Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 and, in the small group market, § 155.705 and § 155.706 of this subchapter;

* * * * *

■ 49. Section 156.350 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 156.350 Eligibility and enrollment standards for Qualified Health Plan issuers on State-based Exchanges on the Federal platform.

(a) * * *

(1) Section 156.285(a)(4)(ii) regarding the premiums for plans offered on the SHOP, for plan years beginning prior to January 1, 2018;

(2) Section 156.285(c)(5) and (c)(8)(iii) regarding the enrollment process for

SHOP, for plan years beginning prior to January 1, 2018; and

* * * * *

■ 50. Section 156.1230 is amended by revising paragraph (b)(2) to read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

* * * * *

(b) * * *

(2) The QHP issuer must engage a third-party entity in accordance with § 155.221 of this subchapter to demonstrate operational readiness and compliance with applicable requirements prior to the QHP issuer's internet website being used to complete a QHP selection.

* * * * *

PART 157—EMPLOYER INTERACTIONS WITH EXCHANGES AND SHOP PARTICIPATION

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

Authority: Title I of the Affordable Care Act, Sections 1311, 1312, 1321, 1411, 1412, Pub. L. 111–148, 124 Stat. 199.

■ 52. Section 157.205 is amended by revising the section heading and adding paragraph (h) to read as follows:

§ 157.205 Qualified employer participation process in a SHOP for plan years beginning prior to January 1, 2018.

* * * * *

(h) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 157.206 is applicable for plan years beginning on or after January 1, 2018.

■ 53. Section 157.206 is added to read as follows:

§ 157.206 Qualified employer participation process in a SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirements.* When joining the SHOP, a qualified employer must comply with the requirements, processes, and timelines set forth by this part and must remain in compliance for the duration of the employer's participation in the SHOP.

(b) *Selecting QHPs.* During an election period, a qualified employer may make coverage in a QHP available through the SHOP in accordance with the processes developed by the SHOP in accordance with § 155.706 of this subchapter.

(c) *Information dissemination to employees.* A qualified employer participating in the SHOP must disseminate information to its qualified employees about the process to enroll in a QHP through the SHOP.

(d) *Employees hired outside of the initial or annual open enrollment period.* Qualified employers must provide employees hired outside of the initial or annual open enrollment period with information about the enrollment process.

(e) *Participation in the SHOP and termination of coverage or enrollment through the SHOP.* (1) Changes affecting participation. Employers must submit a new single employer application to the SHOP or withdraw from participating in the SHOP if the employer makes a change that could end its eligibility under § 155.710 of this subchapter.

(2) If an employer receives a determination of ineligibility to participate in the SHOP or the SHOP terminates its eligibility to participate in the SHOP, unless the SHOP notifies the issuer or issuers of the determination of ineligibility or termination of eligibility, the employer must notify the issuer or issuers of QHPs in which their group members are enrolled in coverage of its ineligibility or termination of eligibility within 5 business days of the end of any applicable appeal process under § 155.741 of this subchapter, which could include when the time to file an appeal lapses without an appeal being filed, when the appeal is rejected or dismissed, or when the appeal process concludes with an adjudication by the appeals entity, as applicable.

(3) Employers must promptly notify the issuer or issuers of QHPs in which their group members are enrolled in coverage if it wishes to terminate coverage or enrollment through the SHOP, unless the SHOP notifies the issuer or issuers.

(f) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 54. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18), as amended.

■ 55. Section 158.170 is amended by revising paragraph (b) introductory text to read as follows:

§ 158.170 Allocation of expenses.

* * * * *

(b) *Description of the methods used to allocate expenses.* The report required in § 158.110 must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses (unless the report utilizes the percentage of premium option described in § 158.221(b)(8), in which case the allocation method description should state so), Federal and State taxes and licensing or regulatory fees, and other non-claims costs, to each health insurance market in each State. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

* * * * *

■ 56. Section 158.221 is amended by adding paragraph (b)(8) to read as follows:

§ 158.221 Formula for calculating an issuer's medical loss ratio.

* * * * *

(b) * * *

(8) Beginning with the 2017 MLR reporting year, an issuer has the option of reporting an amount equal to 0.8 percent of earned premium in the relevant State and market in lieu of reporting the issuer's actual expenditures for activities that improve health care quality, as defined in §§ 158.150 and 158.151. If an issuer chooses this method of reporting, it must apply it for a minimum of 3 consecutive MLR reporting years and for all of its individual, small group, and large group markets; and all affiliated issuers must choose the same reporting method.

* * * * *

■ 57. Section 158.301 is revised to read as follows:

§ 158.301 Standard for adjustment to the medical loss ratio.

The Secretary may adjust the MLR standard that must be met by issuers offering coverage in the individual market in a State, as defined in section 2791 of the PHS Act, for a given MLR reporting year if, in the Secretary's discretion, the Secretary determines that there is a reasonable likelihood that an adjustment to the 80 percent MLR standard of section 2718(b)(1)(A)(ii) of the Public Health Service Act will help stabilize the individual market in that State.

■ 58. Section 158.321 is revised to read as follows:

§ 158.321 Information regarding the State's individual health insurance market.

(a) Subject to § 158.320, the State must provide, for each issuer who actively offers coverage in the individual market in the State, the following information, in accordance with paragraph (b) of this section, for

the preceding calendar year and, at the State's option, for the current year:

(1) Total earned premium and incurred claims;

(2) Total number of enrollees (life-years and covered lives);

(3) Total agents' and brokers' commission expenses;

(4) Net underwriting gain;

(5) Risk-based capital level; and

(6) Whether the issuer has provided notice to the State's insurance commissioner, superintendent, or comparable State authority that the issuer will cease or begin offering individual market coverage on the Exchange, certain geographic areas, or the entire individual market in the State.

(b) The information required in paragraphs (a)(1) through (4) and (6) of this section must be provided separately for the issuer's individual market plans grouped by the following categories, as applicable: On-Exchange, off-Exchange, grandfathered health plans as defined in § 147.140 of this subchapter, coverage that meets the criteria for transitional policies outlined in applicable guidance, and non-grandfathered single risk pool coverage. The information required in paragraph (a)(5) of this section must be provided at the issuer level.

(c) The State must also provide information regarding whether any issuer other than those described in paragraph (a) of this section has provided notice to the State's insurance commissioner, superintendent, or comparable State authority that the issuer will cease or begin offering individual market coverage on the Exchange, certain geographic areas, or the entire individual market in the State.

■ 59. Section 158.322 is revised to read as follows:

§ 158.322 Proposal for adjusted medical loss ratio.

A State must provide its own proposal as to the adjustment it seeks to the MLR standard. This proposal must include an explanation of how an adjustment to the MLR standard for the State's individual market will help stabilize the State's individual market.

■ 60. Section 158.330 is revised to read as follows:

§ 158.330 Criteria for assessing request for adjustment to the medical loss ratio.

The Secretary may consider the following criteria in assessing whether an adjustment to the 80 percent MLR standard, as calculated in accordance with this subpart, would be reasonably likely to help stabilize the individual market in a State that has requested such adjustment:

(a) The number and financial performance (based on data provided by a State under § 158.321) of issuers actively offering individual health insurance coverage on- and off-Exchange, grandfathered health plans as defined in § 147.140 of this subchapter, coverage that meets the criteria for transitional policies outlined in applicable guidance, and non-grandfathered single risk pool coverage; the number of issuers reasonably likely to cease or begin offering individual market coverage in the State; and the likelihood that an adjustment to the 80 percent MLR standard could help increase competition in the individual market in the State, including in underserved areas.

(b) Whether an adjustment to the 80 percent MLR standard for the individual market may improve consumers' access to agents and brokers.

(c) The capacity of any new issuers or issuers remaining in the individual market to write additional business in the event one or more issuers were to cease offering individual market coverage on the Exchange, in certain geographic areas, or in the entire individual market in the State.

(d) The impact on premiums charged, and on benefits and cost sharing provided, to consumers by issuers remaining in or entering the individual market in the event one or more issuers were to cease or begin offering individual market coverage on the Exchange, in certain geographic areas, or in the entire individual market in the State.

(e) Any other relevant information submitted by the State's insurance commissioner, superintendent, or comparable official in the State's request.

■ 61. Section 158.341 is revised to read as follows:

§ 158.341 Treatment as a public document.

A State's request for an adjustment to the MLR standard, and all information submitted as part of its request, will be treated as a public document. Instructions for how to access documents related to a State's request for an adjustment to the MLR standard will be made available on the Secretary's website.

■ 62. Section 158.350 is revised to read as follows:

§ 158.350 Subsequent requests for adjustment to the medical loss ratio.

A State that has made a previous request for an adjustment to the MLR standard must, in addition to the other information required by this subpart, submit information as to what steps the State has taken since its prior requests, if any, to improve the stability of the State's individual market.

Dated: March 6, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: March 28, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–07355 Filed 4–9–18; 4:15 pm]

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FEDERAL REGISTER

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Part III

The President

Proclamation 9725—Pan American Day and Pan American Week, 2018

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Title 3—

The President

Proclamation 9725 of April 12, 2018

Pan American Day and Pan American Week, 2018

By the President of the United States of America

A Proclamation

On Pan American Day and during Pan American Week, we commemorate the 128th anniversary of the First International Conference of American States, which concluded on April 14, 1890, and paved the way for the establishment of the Organization of American States in 1948. As the Organization of American States celebrates the 70th anniversary of its founding this year, the United States reaffirms our commitment to partner with the nations of the Americas to advance security, economic and energy prosperity, and democratic governance throughout the hemisphere.

This week, Vice President Pence will join with leaders in the Pan American region to address corruption and develop strategies to defeat transnational criminal organizations in our hemisphere. During the eighth Summit of the Americas, the United States will look to strengthen the region's collective commitment to representative democracy, to government accountability, and to confront threats to freedom.

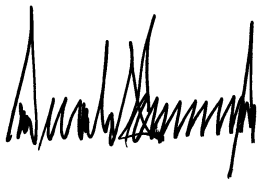
Tragically, the core tenets of free society have been abandoned in Venezuela and Cuba. Our hemispheric community of democracies must support the Venezuelan people and their right to have a voice in their government through free, fair, and internationally validated elections. Furthermore, the United States will not cease in its efforts to secure a future of freedom, peace, and prosperity for the people of Cuba.

Under my Administration, the United States will continue to be a steady, enduring partner to Latin American and Caribbean countries. The United States will continue bilateral discussions on efforts to disrupt the organized crime organizations and trafficking routes that harm our citizens and drive irregular migration. My Administration supports ongoing regional security coordination through programs such as the Merida Initiative in Mexico, the Central American Regional Security Initiative, and the Caribbean Basin Security Initiative, as well as regular meetings, including our Strategic Dialogue to Disrupt Transnational Criminal Organizations with Mexico. At the heart of our engagement is the belief that by working together we can achieve a more prosperous and secure future for our region.

As we observe Pan American Day and Pan American Week, let us capitalize on this momentum and build on our common history with a mutual purpose to achieve hemispheric peace and prosperity.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 14, 2018, as Pan American Day and April 8 through April 14, 2018, as Pan American Week. I urge the Governors of the 50 States, the Governor of the Commonwealth of Puerto Rico, and the officials of the other areas under the flag of the United States of America to honor these observances with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this twelfth day of April, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-second.



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H.R. 4547/P.L. 115–165
Strengthening Protections for Social Security Beneficiaries Act of 2018 (Apr. 13, 2018; 132 Stat. 1257)

S. 772/P.L. 115–166
Ashlynne Mike AMBER Alert in Indian Country Act (Apr. 13, 2018; 132 Stat. 1274)

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