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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2021-500; Project Identifier 2017-SW-069-AD; Amendment 39-21720; AD 2021-19-02]

RIN 2120-AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Helicopters Model EC130B4 and EC130T2 helicopters. This AD was prompted by a report of a jammed pilot collective pitch lever (collective). This AD requires inspecting the collective for proper engagement of the locking pin. The FAA is issuing this AD to address the unsafe condition on these products. **DATES:** This AD is effective November 1, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of November 1, 2021.

ADDRESSES: For service information identified in this final rule, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at <https://www.airbus.com/helicopters/services/technical-support.html>. You may view the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110. It is also available at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-500.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-500; 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 European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, any comments received, and other information. The street address for Docket Operations is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Anthony Kenward, Aviation Safety Engineer, Fort Worth ACO Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5152; email anthony.kenward@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Airbus Helicopters Model EC130B4 and Model EC130T2 helicopters. The NPRM published in the **Federal Register** on July 7, 2021 (86 FR 35695). In the NPRM, the FAA proposed to require, within 90 hours time-in-service (TIS) after the effective date of the AD, or before the next autorotation training flight, whichever occurs first, removing the protective boot along the collective and measuring the clearance between the collective tab hook (hook) and low pitch locking pin (pin). If the clearance is less than 5 mm (0.196 in), adjusting the clearance between the hook and the pin to prevent interference was proposed. The NPRM then proposed to require re-installing the protective boot in accordance with the manufacturer's service information. The NPRM was prompted by EASA AD 2017-0062, dated April 11, 2017 (EASA AD 2017-0062), issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for Airbus Helicopters Model EC130B4 and EC130T2 helicopters. EASA states that during an autorotation test conducted during an acceptance flight, the pilot felt a jamming sensation when pushing

the collective to the low pitch position, and he subsequently was able to free the collective by pulling on it. According to EASA, an analysis determined that the hook and the pin were extremely close, and that a fold in the control lever boot may have become caught between the two components. EASA states that this condition, if not detected and corrected, could result in an untimely locking of the collective and subsequent reduced control of the helicopter.

Accordingly, EASA AD 2017-0062 requires inspecting and adjusting, if necessary, the clearance between the hook and the pin while in the low pitch position.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these helicopters.

Related Service Information Under 14 CFR Part 51

The FAA reviewed Airbus Helicopters Alert Service Bulletin ASB No. EC130-67A019, Revision 0, dated February 23, 2016, which specifies inspecting and adjusting the clearance between the hook and pin.

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.

Differences Between This AD and the EASA AD

The EASA AD requires compliance within 165 hours TIS or 3 months, whichever occurs first. Since the unsafe condition occurred at a collective position commanded during an autorotation, this AD requires compliance within 90 hours TIS after

the effective date of this AD or before the next autorotation training flight, whichever occurs first. Based on the average fleet usage, 90 hours TIS corresponds with the 3-month compliance requirement of the EASA AD.

Costs of Compliance

The FAA estimates that this AD affects 214 helicopters of U.S. Registry. At an average labor rate of \$85 per work-hour, the FAA estimates that operators may incur the following costs in order to comply with this AD. Removing the protective boot will require about 2 work-hours for a cost of \$170 per helicopter and a cost of \$36,380 for the U.S. fleet. Determining the clearance between the hook and pin will require about 0.5 work-hour, for a cost of \$43 per helicopter and a cost of \$9,202 for the U.S. fleet. If required, adjusting the clearance will take about 2 work-hours for a cost of \$170 per helicopter. Re-installing the protective boot will require about 2 work-hours, for a cost of \$170 per helicopter and a cost of \$36,380 for the U.S. fleet.

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.

The FAA is 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 helicopters identified in this rulemaking action.

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) Will not affect intrastate aviation in Alaska, and

(3) 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 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:

2021-19-02 Airbus Helicopters:

Amendment 39-21720 Docket No. FAA-2021-500; Project Identifier 2017-SW-069-AD.

(a) Effective Date

This airworthiness directive (AD) is effective November 1, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Model EC130B4 and Model EC130T2 helicopters, certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6700, Rotorcraft flight control.

(e) Unsafe Condition

This AD was prompted by a report of a jammed pilot collective pitch lever (collective). The FAA is issuing this AD to prevent an untimely locking of the collective and subsequent reduced control of the helicopter.

(f) Compliance

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

(g) Required Actions

Within 90 hours time-in-service after the effective date of this AD or before the next autorotation training flight, whichever occurs first:

(1) For each collective, remove the protective boot along the collective and measure the clearance between the edge of the collective tab hook (a) and the edge of the low pitch locking pin (b) as shown in Figure

1 of Airbus Helicopters Alert Service Bulletin ASB No. EC130-67A019, Revision 0, dated February 23, 2016 (ASB EC130-67A019). If the clearance is less than 5 mm (0.196 in), before further flight:

(i) Adjust the clearance by following the Accomplishment Instructions, paragraph 3.B.3., of ASB EC130-67A019.

(ii) Test the collective for proper engagement of the low pitch locking pin by following the Accomplishment Instructions, paragraph 3.B.4., of ASB EC130-67A019.

(2) Re-install the protective boot on the collective, ensuring that no boot folds have entered the space between the collective tab hook and the low pitch locking pin, by following the Accomplishment Instructions, paragraph 3.B.5., of ASB EC130-67A019.

(h) Special Flight Permits

Special flight permits are prohibited.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@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.

(j) Related Information

(1) For more information about this AD, contact Anthony Kenward, Aviation Safety Engineer, Fort Worth ACO Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5152; email anthony.kenward@faa.gov.

(2) The subject of this AD is addressed in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD 2017-0062, dated April 11, 2017. You may view the EASA AD at <https://www.regulations.gov> in Docket No. FAA-2021-500.

(k) Material Incorporated by Reference

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

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

(i) Airbus Helicopters Alert Service Bulletin ASB No. EC130-67A019, Revision 0, dated February 23, 2016.

(ii) [Reserved]

(3) For service information identified in this AD, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at <https://www.airbus.com>

www.airbus.com/helicopters/services/technical-support.html.

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: fr.inspection@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on August 30, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021-20824 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2021-0507; Project Identifier 2018-SW-117-AD; Amendment 39-21712; AD 2021-18-11]

RIN 2120-AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Leonardo S.p.a. Model AB139 and AW139 helicopters. This AD was prompted by a report that, during a post-flight inspection of an in-service helicopter, a tail rotor slider assembly was found fractured, and the bushing and the actuator rod in the tail rotor servo were partially damaged. This AD requires an inspection of the tail rotor slider assembly for corrosion and signs of circumferential refinishing and, depending on the findings, replacement of the tail rotor slider assembly with a serviceable part or repetitive inspections of the tail rotor slider assembly for corrosion and signs of circumferential refinishing, as specified in a European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 1, 2021.

The Director of the Federal Register approved the incorporation by reference

of a certain publication listed in this AD as of November 1, 2021.

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this IBR material on the EASA website at <https://ad.easa.europa.eu>. You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N 321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110. It is also available in the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0507.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0507; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228-7330; email andrea.jimenez@faa.gov. nyaco-cos@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018-0292, dated December 28, 2018 (EASA AD 2018-0292) (also referred to as the MCAI), to correct an unsafe condition for Leonardo S.p.a. (formerly Finmeccanica S.p.A., AgustaWestland S.p.A., Agusta S.p.A.; AgustaWestland Philadelphia Corporation, formerly Agusta Aerospace Corporation) Model AB139 and AW139 helicopters, all serial numbers. Although EASA AD 2018-0292 applies to all Model AB139 and AW139 helicopters, this AD applies to helicopters with an affected part installed instead.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Leonardo S.p.a. Model AB139 and AW139 helicopters. The NPRM published in the **Federal Register** on June 24, 2021 (86 FR 33149). The NPRM was prompted by a report that, during a post-flight inspection of an in-service helicopter, a tail rotor slide assembly was found fractured, and the bushing and the actuator rod in the tail rotor servo were partially damaged. The subsequent investigation revealed that the failure was due to fatigue, initiated from corroded areas (corrosion craters) on the surface of the tail rotor slider assembly characterized by signs of circumferential refinishing. The corrosion craters originated along finishing signs consistent with low grit sanding operations, which can remove the passivation corrosion protection from the tail rotor slider assembly. Sanding is a maintenance activity that is not included in the maintenance manual for Leonardo S.p.a. Model AB139 and AW139 helicopters and is not allowed on in-service helicopters. The NPRM proposed to require an inspection of the tail rotor slider assembly for corrosion and signs of circumferential refinishing and, depending on the findings, replacement of the tail rotor slider assembly with a serviceable part or repetitive inspections of the tail rotor slider assembly for corrosion and signs of circumferential refinishing, as specified in EASA AD 2018-0292.

The FAA is issuing this AD to address corrosion in the tail rotor slider assembly caused by improper refinishing (characterized by signs of circumferential refinishing consistent with sanding). The unsafe condition, if not addressed, could result in fatigue crack and fracture of the tail rotor slider assembly, resulting in failure of the tail rotor controls and consequent loss of yaw control of the helicopter. See EASA AD 2018-0292 for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Except for minor editorial changes, this AD is

adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products.

Related Service Information Under 1 CFR Part 51

EASA AD 2018–0292 requires a detailed inspection of the tail rotor slide assembly for corrosion and sign of circumferential refinishing and,

depending on the findings, applicable corrective actions. If there is any evidence of corrosion craters the corrective action is replacement of the affected part with a serviceable part. If there is any evidence of surface imperfections caused by circumferential refinishing but no evidence of corrosion, the corrective action is repetitive inspections of the tail rotor slide assembly for corrosion and signs of circumferential refinishing. Replacement of an affected part with a

serviceable part is terminating action for the repetitive inspections.

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

Costs of Compliance

The FAA estimates that this AD affects 129 helicopters of U.S. Registry. The FAA estimates the following costs to comply with this AD.

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$10,965

The FAA estimates the following costs to do any necessary replacement that would be required based on the

results of the inspection. The agency has no way of determining the number of

aircraft that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	Up to 10 work-hours × \$85 per hour = \$850	\$23,200	Up to \$24,050.
Inspection	1 work-hour × \$85 per hour = \$85 per inspection cycle	0	\$85 per inspection cycle.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

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.

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

Regulatory Findings

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

2021–18–11 Leonardo S.p.a.: Amendment 39–21712; Docket No. FAA–2021–0507; Project Identifier 2018–SW–117–AD.

(a) Effective Date

This airworthiness directive (AD) is effective November 1, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Leonardo S.p.a. Model AB139 and AW139 helicopters, certificated in any category, with an affected part as identified in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD 2018–0292, dated December 28, 2018 (EASA AD 2018–0292).

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6400, Tail Rotor System.

(e) Unsafe Condition

This AD was prompted by a report that, during a post-flight inspection of an in-service helicopter, a tail rotor slider assembly was found fractured, and the bushing and the actuator rod in the tail rotor servo were partially damaged. The FAA is issuing this AD to address corrosion in the tail rotor slider assembly caused by improper refinishing (characterized by signs of circumferential refinishing consistent with

sanding). The unsafe condition, if not addressed, could result in fatigue cracks and fracture of the tail rotor slider assembly, resulting in failure of the tail rotor controls and consequent loss of yaw control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2018–0292.

(h) Exceptions to EASA AD 2018–0292

(1) Where EASA AD 2018–0292 refers to flight hours (FH), this AD requires using hours time-in-service.

(2) Where EASA AD 2018–0292 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where EASA AD 2018–0292 refers to “Part I of the ASB,” this AD requires using “Part I of section 3., Accomplishment Instructions of the ASB,” and where EASA AD 2018–0292 refers to “Part II of the ASB,” this AD requires using “Part II of section 3., Accomplishment Instructions of the ASB.”

(4) Where the service information referred to in EASA AD 2018–0292 specifies to return certain parts, this AD does not include that requirement.

(5) Where the service information referred to in EASA AD 2018–0292 specifies to contact Leonardo S.p.a. “if in doubt” regarding if a tail rotor slider assembly needs to be replaced based on evidence of corrosion craters, replacement of an affected slider assembly is required by this AD but contacting Leonardo S.p.a. is not required by this AD.

(6) The “Remarks” section of EASA AD 2018–0292 does not apply to this AD.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2018–0292 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@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.

(k) Related Information

For more information about this AD, contact Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7330; email andrea.jimenez@faa.gov.

(l) Material Incorporated by Reference

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

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

(i) European Aviation Safety Agency (EASA) AD 2018–0292, dated December 28, 2018.

(ii) [Reserved]

(3) For EASA AD 2018–0292, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADS@easa.europa.eu; internet www.easa.europa.eu. You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>.

(4) You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N 321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. This material may be found in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0507.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on August 26, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–20827 Filed 9–24–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0724; Project Identifier MCAI–2021–00321–R; Amendment 39–21723; AD 2021–19–05]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Leonardo S.p.a. Model AB412 and AB412 EP helicopters. This AD was prompted by a report of a cracked hoist support assembly having a certain part number. This AD requires a one-time inspection of the hoist support assembly and, depending on the findings, replacement with a serviceable part, as specified in a European Union Aviation Safety Agency (EASA) Emergency AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective October 12, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 12, 2021.

The FAA must receive comments on this AD by November 12, 2021.

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 <https://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 EASA material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADS@easa.europa.eu; internet www.easa.europa.eu. You may find this IBR material on the EASA website at <https://ad.easa.europa.eu>. You may view the EASA material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of the EASA material at the FAA, call (817) 222–5110. The EASA material is also available at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0724.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0724; 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

AD, the EASA AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT:

Darren Gassetto, Aerospace Engineer, COS Program Management Section, FAA, Operational Safety Branch, Compliance & Airworthiness Division, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone (516) 228-7323; email Darren.Gassetto@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA Emergency AD 2021-0072-E, dated March 12, 2021 (EASA Emergency AD 2021-0072-E) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for Leonardo S.p.a. (formerly AgustaWestland S.p.A., Agusta S.p.A., and Costruzioni Aeronautiche Giovanni Agusta) Model AB412 and AB412 EP helicopters, all serial numbers.

This AD was prompted by a report of a cracked hoist support assembly having part number (P/N) 212-8800-02-1 on a Leonardo S.p.a. Model AB412 military helicopter. The investigation is still ongoing. This same part is installed on Leonardo S.p.a. Model AB412 civil helicopters. The FAA is issuing this AD to address cracking in a hoist support assembly which, if not addressed, could affect the structural integrity of the hoist support assembly, leading to in-flight detachment of the hoist assembly, and possibly resulting in damage to, and reduced control of, the helicopter. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA Emergency AD 2021-0072-E specifies procedures for a one-time inspection of any hoist support assembly having P/N 212-8800-02-1 for cracking and, depending on the findings, replacement with a serviceable part. EASA Emergency AD 2021-0072-E also specifies reporting the inspection results to Leonardo S.p.a.

This material 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

These products have been approved by the aviation authority of another

country, and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is issuing this AD after evaluating all pertinent information and determining that the unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Requirements of This AD

This AD requires accomplishing the actions specified in EASA Emergency AD 2021-0072-E, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities to use this process. As a result, EASA Emergency AD 2021-0072-E is incorporated by reference in this FAA final rule. This AD, therefore, requires compliance with EASA Emergency AD 2021-0072-E in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to "all required actions and compliance times," compliance with this AD requirement is not limited to the section titled "Required Action(s) and Compliance Time(s)" in the EASA AD. Service information specified in EASA Emergency AD 2021-0072-E that is required for compliance with EASA Emergency AD 2021-0072-E is available on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0724.

Interim Action

The FAA considers this AD interim action. If final action is later identified, the FAA might consider further rulemaking then.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for "good cause" finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

There are currently no domestic operators of these products. Therefore, the FAA finds that notice and opportunity for prior public comment are unnecessary pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the foregoing reason, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under **ADDRESSES**. Include "Docket No. FAA-2021-0724; Project Identifier MCAI-2021-00321-R" at the beginning of your comments. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this AD because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to <https://www.regulations.gov>, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and

that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Darren Gassetto, Aerospace Engineer, COS Program Management Section, FAA, Operational Safety Branch, Compliance & Airworthiness Division, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone (516) 228-7323; email Darren.Gassetto@faa.gov. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act (RFA)

The requirements of the RFA do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

There are no costs of compliance with this AD because there are no helicopters with this type certificate on the U.S. Registry.

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 Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Pkwy., Fort Worth, TX 76177-1524.

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.

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

Regulatory Findings

The FAA determined that this AD would not have federalism implications under Executive Order 13132. This 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 regulation:

- (1) Is not a "significant regulatory action" under Executive Order 12866, and
- (2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

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:

2021-19-05 Leonardo S.p.a.: Amendment 39-21723; Docket No. FAA-2021-0724; Project Identifier MCAI-2021-00321-R.

(a) Effective Date

This airworthiness directive (AD) becomes effective October 12, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Leonardo S.p.a. Model AB412 and AB412 EP helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Codes 2500, Cabin Equipment/Furnishings; 2550, Cargo Compartments.

(e) Unsafe Condition

This AD was prompted by a report of a cracked hoist support assembly on a Leonardo S.p.a. Model AB412 military helicopter. The FAA is issuing this AD to address cracking in a hoist support assembly which, if not addressed, could affect the structural integrity of the hoist support assembly, leading to in-flight detachment of the hoist assembly, and possibly resulting in damage to, and reduced control of, the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) Emergency AD 2021-0072-E, dated March 12, 2021 (EASA Emergency AD 2021-0072-E).

(h) Exceptions to EASA Emergency AD 2021-0072-E

(1) Where EASA Emergency AD 2021-0072-E refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not require the "Remarks" section of EASA Emergency AD 2021-0072-E.

(i) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the helicopter to a location where the helicopter can be modified (if the operator elects to do so), provided the hoist is not used until the inspection and any applicable corrective actions specified in paragraphs (1) and (2) of EASA Emergency AD 2021-0072-E are completed.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@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.

(k) Related Information

For more information about this AD, contact Darren Gassetto, Aerospace Engineer, COS Program Management Section, FAA, Operational Safety Branch, Compliance & Airworthiness Division, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone (516) 228-7323; email Darren.Gassetto@faa.gov.

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) Emergency AD 2021-0072-E, dated March 12, 2021.

(ii) [Reserved]

(3) For EASA Emergency AD 2021-0072-E, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>.

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817-222-5110. This material may be found in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0724.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on August 31, 2021.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021-20826 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2021-0721; Project Identifier MCAI-2020-00616-R; Amendment 39-21713; AD 2021-18-12]

RIN 2120-AA64

Airworthiness Directives; PZL Swidnik S.A. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain PZL Swidnik S.A. Model PZL W-3A helicopters. This AD was prompted by a report of fractured hoist carrying assembly bracket (bracket) bolts. This AD requires repetitively inspecting the sealing compound of certain part-numbered brackets, and depending on the results, removing the hoist or removing the hardware from service and installing new hardware. As an option to replacing the bolts, this AD allows deactivating the hoist, turning the circuit breaker panel switches to the OFF position, installing inoperative placards on the circuit breaker panel switches, and before each flight, inspecting the sealing compound. This AD also establishes a life limit for the bracket bolts, and prohibits installing an affected hoist or an affected bracket and hoist unless the actions required by this AD have been accomplished. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective October 12, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of October 12, 2021.

The FAA must receive comments on this AD by November 12, 2021.

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 <https://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 final rule, contact WSK "PZL-Swidnik" S.A., Al. Lotników Polskich 1, 21-045 Świdnik, Poland; telephone (+48) 81722 5716; fax (+48) 81722 5625; email: PL-CustomerSupport.AW@leonardocompany.com; or at <https://www.pzlswidnik.pl/en/home>. You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110. It is also available at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0721.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0721; 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 European Union Aviation Safety Agency (EASA) AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Fred Guerin, Aerospace Engineer, General Aviation & Rotorcraft Section, International Validation Branch, Compliance & Airworthiness Division, FAA, 2200 S 216th St., Des Moines, WA 98198; telephone (202) 267-7457; email fred.guerin@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA Emergency AD 2019-0191-E, dated July 31, 2019 (EASA Emergency AD 2019-0191-E), to correct an unsafe condition for Wytwórnia Sprzętu Komunikacyjnego (WSK) "PZL-Swidnik" Spółka Akcyjna (S.A.) Model PZL W-3A helicopters. EASA advises of a report of fractured bracket bolts. This condition, if not addressed, could result in detachment of the bracket resulting in movement of the hoist carrying assembly around the axis of the remaining two lower brackets, and subsequent damage to the helicopter and loss of hoisted load or person(s).

Accordingly, EASA Emergency AD 2019-0191-E requires repetitive inspections of the sealing compound around the affected brackets and, depending on the findings, accomplishing applicable corrective actions. EASA Emergency AD 2019-

0191-E also requires repetitive replacement of the affected bolts. EASA considers its AD an interim action and states that further AD action may follow.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is issuing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed WYTWÓRNIA SPRZĘTU KOMUNIKACYJNEGO "PZL-Świdnik" Spółka Akcyjna Mandatory Bulletin No. BO-37-19-296, dated July 30, 2019. This service information specifies procedures for repetitively inspecting the sealing compound along the edges of bracket part number (P/N) 39.30.205.03.01 and 39.30.213.00.00. If there is any cracked sealing compound, this service information specifies procedures for removing the hoist and prohibits installing and using the hoist until corrective action is available. If no cracks are found in the sealing compound, this service information specifies procedures for replacing the bolts with new bolts if the hoist is intended to be used and procedures for deactivating the hoist if the hoist is not intended to be used. This service information also specifies a life limit for the bracket bolts.

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.

AD Requirements

For helicopters with a hoist type 76378 installed, this AD requires repetitively cleaning and inspecting the sealing compound around the bracket edges and near each nut for cracked sealing compound. If there is any cracked sealing compound, this AD requires removing the hoist from service. If there is not any cracked sealing compound, this AD requires removing the bolts from service and installing new bolts. As an option to replacing the bolts, this AD allows deactivating the hoist, turning the circuit breaker panel switches to the OFF position, installing inoperative placards on the circuit breaker panel

switches, and before each flight, inspecting the sealing compound. This AD also establishes a life limit for the bolts. Lastly, this AD prohibits installing an affected hoist or an affected bracket and hoist unless the actions required by this AD have been accomplished.

Differences Between This AD and the EASA AD

EASA Emergency AD 2019-0191-E requires using extraction naphtha, whereas this proposed AD would allow using aliphatic naphtha or extraction naphtha. This proposed AD would require removing each previously-installed bracket bolt, nut, washer, and cotter pin from service, whereas EASA AD 2019-0191-E does not. This proposed AD would count a cycle anytime the cable is extended and then retracted during flight or on the ground, whereas EASA Emergency AD 2019-0191-E does not clarify the conditions used for cycle counting. EASA Emergency AD 2019-0191-E allows, in lieu of replacing bolts or removing the hoist, operation of a helicopter with the hoist installed, provided the hoist is deactivated and its use is prohibited and the sealing compound of the affected bracket is inspected before each flight. This AD allows that provision only if there is not any cracked sealing compound.

Interim Action

The FAA considers this AD to be an interim action. If final action is later identified, the FAA might consider further rulemaking.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for "good cause," finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

There are no helicopters with this type certificate on the U.S. Registry. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the foregoing reason, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making

this amendment effective in less than 30 days.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under ADDRESSES. Include "Docket No. FAA-2021-0721; Project Identifier MCAI-2020-00616-R" at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to <https://www.regulations.gov>, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Fred Guerin, Aerospace Engineer, General Aviation & Rotorcraft Section, International Validation Branch, Compliance & Airworthiness Division, FAA, 2200 S 216th St., Des Moines, WA 98198; telephone (202) 267-7457; email fred.guerin@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without

prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

Costs of Compliance

There are no costs of compliance with this AD because there are no helicopters with this type certificate on the U.S. Registry.

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.

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

Regulatory Findings

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, I certify that this AD:

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

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:

2021–18–12 PZL Swidnik S.A.:

Amendment 39–21713; Docket No. FAA–2021–0721; Project Identifier MCAI–2020–00616–R.

(a) Effective Date

This airworthiness directive (AD) is effective October 12, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to PZL Swidnik S.A. Model PZL W–3A helicopters, certificated in any category, with hoist type 76378 or hoist carrying assembly bracket (bracket) part number (P/N) 39.30.205.03.01 or 39.30.213.00.00 installed.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 2500, Cabin Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by a report of fractured bracket bolts. The FAA is issuing this AD to prevent detachment of the bracket resulting in movement of the hoist carrying assembly around the axis of the remaining two lower brackets. The unsafe condition, if not addressed, could result in damage to the helicopter and loss of hoisted load or person(s).

(f) Compliance

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

(g) Required Actions

(1) For helicopters with a hoist type 76378 installed, before further flight after the effective date of this AD:

(i) Clean the area where bracket P/N 39.30.205.03.01 or 39.30.213.00.00 is installed to the fuselage structure using extraction or aliphatic naphtha. Using a flashlight and a magnifying glass with a minimum x5 magnification, inspect around the bracket edge and near each nut for cracked sealing compound. Refer to Figure 1 of WYTWORKNIA SPRZĘTU KOMUNIKACYJNEGO "PZL-Świdnik" Spółka Akcyjna Mandatory Bulletin No. BO–37–19–296, dated July 30, 2019 (MB BO–37–19–296), for an example of cracked sealing compound.

(A) If there is any cracked sealing compound, before further flight, remove the hoist from service. Reinstallation of a hoist type 76378 (that has not been removed from service) is allowed, provided that, before installation, the helicopter is modified in

accordance with a method approved by the Manager, General Aviation and Rotorcraft Section, International Validation Branch, FAA; or EASA; or PZL Swidnik S.A.'s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature. Following modification, all repetitive inspections, replacements, and applicable corrective actions must be done as specified in this AD.

(B) If there are no cracks in the sealing compound, before further flight, replace each bracket bolt one-by-one by following Chapter II, paragraphs A.4.b. through i., of MB BO–37–19–296, except where it states to use extraction naphtha, you may substitute aliphatic naphtha. Remove each previously-installed bracket bolt, nut, washer, and cotter pin from service.

(C) As an option to the actions required by paragraph (g)(1)(i)(B) of this AD, deactivate the hoist by following Chapter II, paragraph 3.2.2., of MB BO–37–19–296; and thereafter, before each flight, inspect the sealing compound by accomplishing the actions required by paragraph (g)(1)(i) of this AD.

(ii) If there are no cracks in the sealing compound, within 25 hours time-in-service (TIS) after the replacement required by paragraph (g)(1)(i)(B) of this AD, and thereafter at intervals not to exceed 25 hours TIS, accomplish the actions required by paragraph (g)(1)(i) of this AD.

(iii) Within 800 hoist cycles after the replacement required by paragraph (g)(1)(i)(B) of this AD, and thereafter at intervals not to exceed 800 hoist cycles, replace each bracket bolt by accomplishing the actions required by paragraph (g)(1)(i)(B) of this AD. For the purposes of this AD, a cycle is counted anytime the cable is extended and then retracted during flight or on the ground, for any cable length extended and retracted and with or without load.

(2) For helicopters with a bracket P/N 39.30.205.03.01 or 39.30.213.00.00 installed, but no hoist installed, as of the effective date of this AD, do not install a hoist type 76378 unless the actions required by paragraph (g)(1) of this AD have been accomplished.

(3) As of the effective date of this AD, do not install bracket P/N 39.30.205.03.01 or 39.30.213.00.00 and hoist type 76378 on any helicopter unless the actions required by paragraph (g)(1) of this AD have been accomplished.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (i)(1) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@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.

(i) Related Information

(1) For more information about this AD, contact Fred Guerin, Aerospace Engineer, General Aviation & Rotorcraft Section, International Validation Branch, Compliance & Airworthiness Division, FAA, 2200 S 216th St., Des Moines, WA 98198; telephone (202) 267-7457; email fred.guerin@faa.gov.

(2) The subject of this AD is addressed in European Union Aviation Safety Agency (EASA) Emergency AD 2019-0191-E, dated July 31, 2019. You may view the EASA AD at <https://www.regulations.gov> in Docket No. FAA-2021-0721.

(j) Material Incorporated by Reference

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

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

(i) WYTŹÓRŹIA SPRZĘTU KOMUNIKACYJNEGO “PZL-Świdnik” Spółka Akcyjna Mandatory Bulletin No. BO-37-19-296, dated July 30, 2019.

(ii) [Reserved]

(3) For service information identified in this AD, contact WSK “PZL-Świdnik” S.A., Al. Lotników Polskich 1, 21-045 Świdnik, Poland; telephone (+48) 81722 5716; fax (+48) 81722 5625; email: PL-CustomerSupport.AW@leonardocompany.com; or at <https://www.pzlswidnik.pl/en/home>.

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: fr.inspection@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on August 26, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021-20828 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2021-0505; Project Identifier 2018-SW-004-AD; Amendment 39-21721; AD 2021-19-03]

RIN 2120-AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Leonardo S.p.a. Model AB139 and AW139 helicopters. This AD was prompted by reports of spurious in-flight disconnections of the automatic flight control system (AFCS). This AD requires updating certain “Primus Epic” system software, as specified in a European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 1, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 1, 2021.

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this material on the EASA website at <https://ad.easa.europa.eu>. You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N 321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110. It is also available in the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0505.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0505; 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 EASA AD, any comments received, and other information. The address for Docket Operations is U.S.

Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L’Enfant Plaza N SW, Washington, DC 20024; telephone 202-267-9167; email hal.jensen@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018-0002, dated January 4, 2018 (EASA AD 2018-0002) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Leonardo S.p.a. Model AB139 and AW139 helicopters.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Leonardo S.p.a. Model AB139 and AW139 helicopters. The NPRM published in the **Federal Register** on July 7, 2021 (86 FR 35690). The NPRM was prompted by reports of spurious in-flight disconnections of the AFCS. The NPRM proposed to require updating certain “Primus Epic” system software, as specified in EASA AD 2018-0002.

The FAA is issuing this AD to address spurious degradation or unavailability of the full AFCS. The unsafe condition, if not addressed, could result in temporary impairment of the automated flight aid for control of the helicopter and increase the flightcrew’s workload. See EASA AD 2018-0002 for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products.

Related Service Information Under 1 CFR Part 51

EASA AD 2018–0002 requires installation of certain “Primus Epic” system software, depending on the helicopter configuration. EASA AD 2018–0002 allows installation of

“Primus Epic” system software on a helicopter after that helicopter has had the software upgrade installed.

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

Costs of Compliance

The FAA estimates that this AD affects 128 helicopters of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Software upgrade	24 work-hours × \$85 per hour = \$2,040	\$0	\$2,040	\$261,120

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

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.

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

Regulatory Findings

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

2021–19–03 Leonardo S.p.a.: Amendment 39–21721; Docket No. FAA–2021–0505; Project Identifier 2018–SW–004–AD.

(a) Effective Date

This airworthiness directive (AD) is effective November 1, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Leonardo S.p.a. Model AB139 and AW139 helicopters, certificated in any category, identified in paragraphs (c)(1) and (2) of this AD, equipped with “Primus Epic” system software release 7.4 (Phase 7 V1), 7.7 (Phase 7 V3) or 7.10 (Phase 7 V4).

(1) Model AB139 and AW19 helicopters having serial number (S/N) 31005, 31006, and S/Ns 31008 through 31157 inclusive; and S/Ns 41001 through 41023 inclusive.

(2) Model AW139 helicopters having S/N 31201 and subsequent, and S/N 41201 and subsequent.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 2200, Auto Flight System.

(e) Unsafe Condition

This AD was prompted by reports of spurious in-flight disconnections of the

automatic flight control system (AFCS). The FAA is issuing this AD to address spurious degradation or unavailability of the full AFCS. The unsafe condition, if not addressed, could result in temporary impairment of the automated flight aid for control of the helicopter and increase the flightcrew’s workload.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD 2018–0002, dated January 4, 2018 (EASA AD 2018–0002).

(h) Exceptions to EASA AD 2018–0002

(1) Where EASA AD 2018–0002 refers to flight hours (FH), this AD requires using hours time-in-service.

(2) Where EASA AD 2018–0002 refers to its effective date, this AD requires using the effective date of this AD.

(3) The “Remarks” section of EASA AD 2018–0002 does not apply to this AD.

(4) Where the service information referenced in EASA AD 2018–0002 specifies to download an option file from a certain website, that method of installation is not required by this AD.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2018–0002 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD.

Information may be emailed to: 9-AVS-AIR-730-AMOC@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.

(k) Related Information

For more information about this AD, contact Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone 202-267-9167; email hal.jensen@faa.gov.

(l) Material Incorporated by Reference

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

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

(i) European Aviation Safety Agency (EASA) AD 2018-0002, dated January 4, 2018.

(ii) [Reserved]

(3) For EASA AD 2018-0002, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>.

(4) You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817-222-5110. This material may be found in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0505.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on August 30, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021-20825 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2021-0785; Project Identifier AD-2021-00989-R; Amendment 39-21734; AD 2021-19-16]

RIN 2120-AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021-16-02, which applied to certain Airbus Helicopters Model SA330J, AS332C, AS332L, AS332L1, AS332L2, and EC225LP helicopters. AD 2021-16-02 required inspecting the locking safety mechanism of the left-hand (LH) side stairway door handle and depending on the results, corrective action. AD 2021-16-02 also required modifying that locking safety mechanism. This AD retains the requirements in AD 2021-16-02, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference, and clarifies a certain exception. This AD was prompted by the need to clarify that exception. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective October 12, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 24, 2021 (86 FR 46771).

The FAA must receive comments on this AD by November 12, 2021.

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 <https://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 material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221

8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this material on the EASA website at <https://ad.easa.europa.eu>. You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110. It is also available in the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0785.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0785; 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 AD, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Hal Jensen, Aerospace Engineer, Operational Safety Branch, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267-9167; email hal.jensen@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued AD 2021-16-02, Amendment 39-21663 (86 FR 46771, August 20, 2021) (AD 2021-16-02), for certain Airbus Helicopters Model SA330J, AS332C, AS332L, AS332L1, AS332L2, and EC225LP helicopters. AD 2021-16-02 required inspecting the locking safety mechanism of the LH side stairway door handle and depending on the results, corrective action. AD 2021-16-02 also required modifying that locking safety mechanism.

AD 2021-16-02 was prompted by EASA AD 2020-0087, dated April 15, 2020 (EASA AD 2020-0087), issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for Airbus Helicopters (AH), formerly Eurocopter, Eurocopter France, Aerospatiale, Sud Aviation, Model SA330J, AS332C, AS332L, AS332L1, AS332L2, and EC225LP helicopters, if equipped with an LH side stairway door, except helicopters modified in accordance with AH modification (MOD) 07 28281 (AS 332, EC 225) or MOD 07 27338 (SA 330). EASA issued EASA AD 2020-0087 to supersede EASA Emergency AD 2014-0241-E, dated November 4, 2014 (EASA AD 2014-0241-E).

The FAA issued AD 2021–16–02 to address incorrect locking of the LH side stairway door, which could result in an in-flight opening of the door and subsequent damage to the helicopter or injury to persons on the ground. See EASA AD 2020–0087 for additional background information.

Actions Since AD 2021–16–02 Was Issued

Since AD 2021–16–02 was issued, the FAA has determined that is necessary to clarify a required exception. As published, paragraph (h)(7) of AD 2021–16–02 could cause confusion with paragraph (h)(5) of AD 2021–16–02. Paragraph (h)(7) of this AD clarifies that the terminating action for the repetitive inspections as required by paragraph (2) of EASA AD 2020–0087 does not apply to this AD. The repetitive inspections as required by paragraph (2) of EASA AD 2020–0087 are not required by paragraph (h)(5) of this AD, and accordingly, this AD cannot provide terminating action for those repetitive inspections.

Related Service Information Under 1 CFR Part 51

EASA AD 2020–0087 requires repetitively inspecting the locking safety mechanism of the LH side stairway door handle for correct operation and depending on the results, reconditioning the locking safety mechanism or contacting the Airbus Helicopters Support and Services Department. EASA AD 2020–0087 also requires modifying the locking safety mechanism, which constitutes terminating action for the repetitive inspections.

This material 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

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is issuing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of these same type designs.

AD Requirements

This AD requires accomplishing the actions specified in EASA AD 2020–0087, described previously, as

incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD and except as discussed under “Differences Between this AD and the EASA AD.”

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA AD 2020–0087 is incorporated by reference in this FAA final rule. This AD, therefore, requires compliance with EASA AD 2020–0087 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2020–0087 does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in the EASA AD. Service information referenced in EASA AD 2020–0087 for compliance will be available at <https://www.regulations.gov> by searching for and locating FAA–2021–0785.

Differences Between This AD and the EASA AD

Where EASA AD 2020–0087 refers to the effective date of EASA AD 2014–0241–E or its effective date, this AD requires using the effective date of this AD. Where EASA AD 2020–0087 refers to Group 1 and 2 helicopters, this AD does not refer to any groups of helicopters. Where the service information referenced in EASA AD 2020–0087 allows the pilot to perform the requirements of the ASB, this AD requires the requirements to be performed by a qualified mechanic. Where the service information referenced in EASA AD 2020–0087 specifies to submit certain information to the manufacturer, this AD does not include that requirement. Where the service information referenced in EASA AD 2020–0087 specifies to discard certain parts, this AD requires removing those parts from service instead. EASA AD 2020–0087 requires repeating the inspection before next flight after each application of painting on the LH side

stairway door or its external door handle, whereas this AD does not. EASA AD 2020–0087 allows a terminating action for the repetitive inspections, whereas this AD does not. EASA AD 2020–0087 requires contacting the Airbus Helicopters Support and Services Department if it is impossible to recondition the locking safety mechanism by moving the door handle, whereas this AD requires, before further flight, accomplishing paragraph (5) of EASA AD 2020–0087 or accomplishing corrective action using a method approved by the Manager, International Validation Branch, FAA. The Manager's approval letter must specifically refer to this AD.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for “good cause,” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

This AD clarifies an exception in AD 2021–16–02 that could affect compliance and the public was previously provided opportunity for comment on the costs of the AD and required actions.

Accordingly, notice and opportunity for prior public comment are unnecessary pursuant to 5 U.S.C. 553(b)(3)(B). In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forgo notice and comment.

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA–2021–0785; Project Identifier AD–2021–00989–R” at the beginning of your comments. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing

date and may amend this AD because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to <https://www.regulations.gov>, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Hal Jensen, Aerospace Engineer, Operational Safety Branch, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267-9167; email hal.jensen@faa.gov. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act (RFA)

The requirements of the RFA do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 37 helicopters of U.S. Registry. Labor rates are estimated at \$85 per work-hour. Based on these numbers, the FAA estimates that operators may incur the following costs in order to comply with this AD.

Inspecting the operation of the locking safety mechanism on the LH side stairway door handle takes about 0.1 work-hour for an estimated cost of \$9 per helicopter and \$333 for the U.S. fleet. Moving the external door handle from the "Locked" to the "Unlocked"

position to determine if the safety mechanism on the LH side stairway door handle can lock automatically takes about 0.5 work-hour for an estimated cost of \$43 per helicopter. Modifying the locking safety mechanism on the LH side stairway door handle takes about 8 work-hours and parts cost about \$5,000 for an estimated cost of \$5,680 per helicopter.

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.

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

Regulatory Findings

The FAA determined that this AD would not have federalism implications under Executive Order 13132. This 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 regulation:

- (1) Is not a "significant regulatory action" under Executive Order 12866, and
- (2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

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:
 - a. Removing Airworthiness Directive 2021-16-02, Amendment 39-21663 (86 FR 46771, August 20, 2021); and
 - b. Adding the following new airworthiness directive:

2021-19-16 Airbus Helicopters:

Amendment 39-21734; Docket No. FAA-2021-0785; Project Identifier AD-2021-00989-R.

(a) Effective Date

This airworthiness directive (AD) becomes effective October 12, 2021.

(b) Affected ADs

This AD replaces AD 2021-16-02, Amendment 39-21663 (86 FR 46771, August 20, 2021) (AD 2021-16-02).

(c) Applicability

This AD applies to Airbus Helicopters Model SA330J, AS332C, AS332L, AS332L1, AS332L2, and EC225LP helicopters, certificated in any category, as identified in the Applicability of European Union Aviation Safety Agency AD 2020-0087, dated April 15, 2020 (EASA AD 2020-0087).

(d) Subject

Joint Aircraft System Component (JASC) Code: 5210, Passenger/Crew Doors.

(e) Unsafe Condition

This AD was prompted by a report of a left-hand (LH) side stairway door that inadvertently opened and tore off from its attachment fittings during flight. The FAA is issuing this AD to address incorrect locking of the LH side stairway door, which could result in an in-flight opening of the door and subsequent damage to the helicopter or injury to persons on the ground.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2020-0087.

(h) Exceptions to EASA AD 2020-0087

(1) Where EASA AD 2020-0087 refers to November 6, 2014 (the effective date of EASA AD 2014-0241-E, dated November 4, 2014) or its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2020-0087 refers to Group 1 and Group 2 helicopters, this AD does not refer to any groups of helicopters.

(3) Where the service information referenced in EASA AD 2020-0087 permits certain actions to be performed by a mechanical engineering technician or pilot, this AD requires that the actions be performed by a qualified mechanic.

(4) Where the service information referenced in EASA AD 2020-0087 specifies

to discard certain parts, this AD requires removing those parts from service.

(5) While paragraph (2) of EASA AD 2020–0087 requires actions before next flight after each application of painting on the LH side stairway door or its external door handle, those actions are not required by this AD.

(6) Where paragraph (3) of EASA AD 2020–0087 requires reconditioning the locking safety mechanism, and the service information referenced in paragraph (3) of EASA AD 2020–0087 specifies contacting the Airbus Helicopters Support and Services Department if it is impossible to recondition the locking safety mechanism by moving the door handle, this AD requires moving the external door handle from the “Locked” to the “Unlocked” position to determine if the safety mechanism can lock automatically. If the safety mechanism does not lock automatically, this AD requires, before further flight accomplishing paragraph (5) of EASA AD 2020–0087 or accomplishing corrective action using a method approved by the Manager, International Validation Branch, FAA. The Manager’s approval letter must specifically refer to this AD.

(7) Where paragraph (5) of EASA AD 2020–0087 identifies the modification as required by paragraph (4) of EASA AD 2020–0087 as terminating action for the repetitive inspections as required by paragraph (2) of EASA AD 2020–0087 for that helicopter, the terminating action for the repetitive inspections as required by paragraph (2) of EASA AD 2020–0087 does not apply to this AD.

(8) This AD does not mandate compliance with the “Remarks” section of EASA AD 2020–0087.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2020–0087 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@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.

(k) Related Information

For more information about this AD, contact Hal Jensen, Aerospace Engineer, Operational Safety Branch, FAA, 950 L’Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267–9167; email hal.jensen@faa.gov.

(l) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on September 24, 2021 (86 FR 46771).

(i) European Union Aviation Safety Agency (EASA) AD 2020–0087, dated April 15, 2020.

(ii) [Reserved]

(4) For EASA AD 2020–0087, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>.

(5) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. This material may be found in the AD docket at <https://www.regulations.gov> by searching for and locating FAA–2021–0785.

(6) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on September 8, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–20464 Filed 9–24–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0723; Project Identifier MCAI–2020–00268–R; Amendment 39–21716; AD 2021–18–15]

RIN 2120–AA64

Airworthiness Directives; PZL Swidnik S.A. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain PZL Swidnik S.A. Model PZL W–3A helicopters. This AD was prompted by a report that displaced teeth were detected on the moveable assemblies of a main rotor (MR) blade droop stop.

This AD requires removing from service the moveable assemblies from each affected MR blade droop stop and prohibits installation of an affected MR blade droop stop and moveable assemblies of affected MR blade droop stops. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective October 12, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of October 12, 2021.

The FAA must receive comments on this AD by November 12, 2021.

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 <https://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 final rule, contact WSK “PZL-Swidnik” S.A., Al. Lotników Polskich 1, 21–045 Świdnik, Poland; telephone (+48) 81722 5716; fax (+48) 81722 5625; email: PL-CustomerSupport.AW@leonardocompany.com; or at <https://www.pzlswidnik.pl/en/home>. You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0723.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0723; 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 European Union Aviation Safety Agency (EASA) AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Andrea Jimenez, Aerospace Engineer,

COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228-7330; email andrea.jimenez@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019-0202, dated August 19, 2019 (EASA AD 2019-0202), to correct an unsafe condition for PZL Swidnik S.A. Model PZL W-3A and PZL W-3AS helicopters all manufacturer serial numbers. Model PZL W-3AS helicopters are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those helicopters in the applicability.

EASA advises that an occurrence was reported where displaced teeth were detected on the moveable assemblies of an MR blade droop stop part number (P/N) 37.21.800.00.00. This condition, if not addressed, could result in erroneous operation of MR blade droop stop teeth during engine start-up or shut-down, or dynamic drop-down of an MR blade, resulting in contact of the affected MR blade with the tail boom, and possibly resulting in injury of occupants or persons on the ground.

Accordingly, EASA AD 2019-0202 requires removal of each affected part from any helicopter on which it is installed and prohibits installation of any affected MR blade droop stop or any moveable assembly of an affected MR blade droop stop on any helicopter.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is issuing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed WYTWÓRNIA SPRZĘTU KOMUNIKACYJNEGO "PZL-Swidnik" Spółka Akcyjna Mandatory Bulletin No. BO-37-18-302, Revision 1, dated July 11, 2019. This service information specifies procedures for removing the moveable assemblies of the MR blade droop stops. The service

information specifies that the MR blade droop stop consists of four retaining washers that are installed on the MR hub flapping hinges and four moveable MR blade droop stop assemblies installed on the retaining washers.

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.

Other Related Service Information

The FAA also reviewed WYTWÓRNIA SPRZĘTU KOMUNIKACYJNEGO "PZL-Swidnik" Spółka Akcyjna Mandatory Bulletin No. BO-37-18-302, dated June 19, 2019. This service information also specifies procedures for removing the moveable assemblies of the MR blade droop stops but does not include the detailed effectivity and scope of compliance that is included in WYTWÓRNIA SPRZĘTU KOMUNIKACYJNEGO "PZL-Swidnik" Spółka Akcyjna Mandatory Bulletin No. BO-37-18-302, Revision 1, dated July 11, 2019.

AD Requirements

This AD requires accomplishing the actions specified in the service information already described.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for "good cause," finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

There are no helicopters with this type certificate on the U.S. Registry. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the foregoing reason, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under ADDRESSES. Include "Docket No. FAA-2021-0723;

Project Identifier MCAI-2020-00268-R" at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to <https://www.regulations.gov>, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228-7330; email andrea.jimenez@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

Costs of Compliance

There are no costs of compliance with this AD because there are no helicopters

with this type certificate on the U.S. Registry.

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.

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

Regulatory Findings

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, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866, and
- (2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

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:

2021–18–15 PZL Swidnik S.A.:
Amendment 39–21716; Docket No. FAA–2021–0723; Project Identifier MCAI–2020–00268–R.

(a) Effective Date

This airworthiness directive (AD) is effective October 12, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to PZL Swidnik S.A. Model PZL W–3A helicopters, certificated in any category, with movable assemblies of main rotor (MR) blade droop stop, part number (P/N) 37.21.800.00.00, installed.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6200, Main Rotor System.

(e) Unsafe Condition

This AD was prompted by a report that displaced teeth were detected on the moveable assemblies of an MR blade droop stop. The FAA is issuing this AD to address displaced teeth on the moveable assemblies of the MR blade droop stop. The unsafe condition, if not addressed, could result in erroneous operation of MR blade droop stop teeth during engine start-up or shut-down, or dynamic drop-down of an MR blade, resulting in contact of the affected MR blade with the tail boom, and possibly resulting in injury of occupants or persons on the ground.

(f) Compliance

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

(g) Required Actions

Within 30 days after the effective date of this AD, remove from service each moveable assembly of MR blade droop stop P/N 37.21.800.00.00 from all MR hub arms, in accordance with Chapter II of WYTWORKIA SPRZĘTU KOMUNIKACYJNEGO "PZL–Świdnik" Spółka Akcyjna Mandatory Bulletin No. BO–37–18–302, Revision 1, dated July 11, 2019.

(h) Part Installation Prohibition

As of the effective date of this AD, no person may install on any helicopter an MR blade droop stop, P/N 37.21.800.00.00, and do not install on any helicopter any movable assembly of an MR blade droop stop, P/N 37.21.800.00.00.

(i) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using WYTWORKIA SPRZĘTU KOMUNIKACYJNEGO "PZL–Świdnik" Spółka Akcyjna Mandatory Bulletin No. BO–37–18–302, dated June 19, 2019.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@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.

(k) Related Information

(1) For more information about this AD, contact Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7330; email andrea.jimenez@faa.gov.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (l)(3) and (4) of this AD.

(3) The subject of this AD is addressed in European Union Aviation Safety Agency (EASA) AD 2019–0202, dated August 19, 2019. You may view the EASA AD at <https://www.regulations.gov> in Docket No. FAA–2021–0723.

(l) Material Incorporated by Reference

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

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

(i) WYTWORKIA SPRZĘTU KOMUNIKACYJNEGO "PZL–Świdnik" Spółka Akcyjna Mandatory Bulletin No. BO–37–18–302, Revision 1, dated July 11, 2019.

(ii) [Reserved]

(3) For service information identified in this AD, contact WSK "PZL–Świdnik" S.A., Al. Lotników Polskich 1, 21–045 Świdnik, Poland; telephone (+48) 81722 5716; fax (+48) 81722 5625; email: PL-CustomerSupport.AW@leonardocompany.com; or at <https://www.pzlswidnik.pl/en/home>.

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: fr.inspection@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on August 26, 2021.

Lance T. Gant,

*Director, Compliance & Airworthiness
Division, Aircraft Certification Service.*

[FR Doc. 2021-20830 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2021-0513; Project Identifier 2018-SW-116-AD; Amendment 39-21717; AD 2021-18-16]

RIN 2120-AA64

Airworthiness Directives; Bell Textron Canada Limited (Type Certificate Previously Held by Bell Helicopter Textron Canada Limited) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bell Textron Canada Limited (Bell) Model 429 helicopters. This AD was prompted by reports of tail rotor gearbox assemblies found loose on the gearbox support. This AD requires repetitive torque checks of the tail rotor gearbox attachment hardware, and corrective action if necessary. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 1, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of November 1, 2021.

ADDRESSES: For service information identified in this final rule, contact Bell Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J 1R4, Canada; telephone 1-450-437-2862 or 1-800-363-8023; fax 1-450-433-0272; email productsupport@bellflight.com; or at <https://www.bellflight.com/support/contact-support>. You may view the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817-222-5110. It is also available at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0513.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2021-0513; 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 Transport Canada AD, any comments received, and other information. The street address for Docket Operations is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Darren Gassetto, Aerospace Engineer, COS Program Management Section, FAA, Operational Safety Branch, Compliance & Airworthiness Division, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone (516) 228-7323; email Darren.Gassetto@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bell Textron Canada Limited (Bell) Model 429 helicopters. The NPRM published in the **Federal Register** on June 28, 2021 (86 FR 33918). In the NPRM, the FAA proposed to require repetitive torque checks of the tail rotor gearbox attachment hardware, and corrective action if necessary. The NPRM was prompted by Canadian AD CF-2018-35, dated December 19, 2018 (Canadian AD CF-2018-35), issued by Transport Canada, which is the aviation authority for Canada, to correct an unsafe condition for Bell Textron Canada Limited Model 429 helicopters. Transport Canada advises that there have been reports of tail rotor gearbox assemblies found loose on the gearbox support. Transport Canada issued Emergency Canadian Airworthiness Directive CF-2018-18, dated July 11, 2018, which corresponds to FAA AD 2018-16-51, Amendment 39-19421 (83 FR 53171, October 22, 2018), to address the immediate safety concern. An ongoing investigation determined that this condition-loose tail rotor gearbox assemblies-could return even after the corrective actions by the previous AD have been completed. This condition, if not addressed, could result in structural

damage and possible loss of control of the helicopter.

Accordingly, Canadian AD CF-2018-35 requires repetitive torque checks of the tail rotor gearbox attachment hardware and corrective actions if necessary. The corrective action is doing additional repetitive torque checks at intervals of 10 to 25 hours air time until the torque stabilizes on all the nuts.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with Canada, Transport Canada, its technical representative, has notified the FAA of the unsafe condition described in its AD. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these helicopters. Except for minor editorial changes, this AD is adopted as proposed in the NPRM.

Related Service Information Under 14 CFR Part 51

The FAA reviewed Bell Alert Service Bulletin 429-18-41, dated July 24, 2018. This service information specifies procedures for repetitive torque checks of the tail rotor gearbox attachment hardware.

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.

Differences Between This AD and the Transport Canada AD

Where Canadian AD CF-2018-35 refers to "200-hour" inspections and "10 to 25 hours air time" for the torque checks, for this AD use "time-in-service" instead.

Costs of Compliance

The FAA estimates that this AD affects 98 helicopters of U.S. Registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Torque check	1 work-hour × \$85 per hour = \$85	\$0	\$85	\$8,330

The FAA estimates the following costs to do any necessary on-condition actions that are required based on the

results of any required actions. The FAA has no way of determining the number

of helicopters that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Action	Labor cost	Parts cost	Cost per product
Repetitive torque check	1 work-hour × \$85 per hour = \$85, per cycle	\$0	\$85, per cycle.

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.

The FAA is 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 helicopters identified in this rulemaking action.

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

2021–18–16 Bell Textron Canada Limited (Type Certificate Previously Held by Bell Helicopter Textron Canada Limited): Amendment 39–21717; Docket No. FAA–2021–0513; Project Identifier 2018–SW–116–AD.

(a) Effective Date

This airworthiness directive (AD) is effective November 1, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bell Textron Canada Limited (type certificate previously held by Bell Helicopter Textron Canada Limited) Model 429 helicopters, certificated in any category, serial numbers 57001 and subsequent.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6500, Tail Rotor Drive System; and 6520, Tail Rotor Gearbox.

(e) Unsafe Condition

This AD was prompted by reports of tail rotor gearbox assemblies found loose on the gearbox support. The FAA is issuing this AD

address tail rotor gearbox assemblies found loose on the gearbox support. The unsafe condition, if not addressed, could result in structural damage and possible loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

Within 12 months after the effective date of this AD; or at the next scheduled 200-hours time-in-service (TIS) or 12-month inspection, whichever occurs first, do a torque check of the tail rotor gearbox attachment hardware, in accordance with the Accomplishment Instructions, paragraph 2., of Bell Alert Service Bulletin 429–18–41, dated July 24, 2018. Repeat the torque check thereafter at intervals not to exceed 200 hours TIS or 12 months, whichever occurs first.

(h) Corrective Actions

If, during any torque check required by paragraph (g) of this AD, any tail rotor gearbox attachment moves during any torque check, repeat the torque check specified in paragraph (g) of this AD at intervals no less than 10 hours TIS and not to exceed 25 hours TIS until the torque stabilizes on all the nuts. Stabilization has occurred when, at the next torque check, the value has remained within the specified acceptable limits (160 to 200 inch-pounds (in-lbs) or 19 to 22 newton meters (Nms), inclusive), preventing movement of the gearbox housing. After the torque stabilizes on all the nuts, the repetitive torque checks specified in paragraph (g) of this AD are still required.

(i) Credit for Previous Actions

This paragraph provides credit for the initial torque check required by paragraph (g) of this AD, if that action was done before the effective date of this AD as required by paragraph (f)(2) of AD 2018–16–51, Amendment 39–19421 (83 FR 53171, October 22, 2018).

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@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.

(k) Related Information

(1) For more information about this AD, contact Darren Gassetto, Aerospace Engineer, COS Program Management Section, FAA, Operational Safety Branch, Compliance & Airworthiness Division, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7323; email Darren.Gassetto@faa.gov.

(2) The subject of this AD is addressed in Transport Canada AD CF-2018-35, dated December 19, 2018. You may view the Transport Canada AD at <https://www.regulations.gov> in Docket No. FAA-2021-0513.

(l) Material Incorporated by Reference

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

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

(i) Bell Alert Service Bulletin 429-18-41, dated July 24, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Bell Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J 1R4, Canada; telephone 1-450-437-2862 or 1-800-363-8023; fax 1-450-433-0272; email productsupport@bellflight.com; or at <https://www.bellflight.com/support/contact-support>.

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817-222-5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: fr.inspection@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on August 26, 2021.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021-20829 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE

International Trade Administration

19 CFR Part 351

Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions

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

ACTION: Notification and guidance.

SUMMARY: On September 20, 2021, the Department of Commerce (Commerce) published the final rule entitled “Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws” in the *Federal Register* (*Final Rule*). In the *Final Rule*, Commerce explained that it would make available an application for parties to fill out and submit to request a scope inquiry and ruling and that it would provide additional instruction on the procedures for the annual inquiry service list, as appropriate. This document provides further information on the availability of the scope ruling application through Commerce’s website and the additional procedures to request placement on the annual inquiry service list. In addition, Commerce is notifying the public that it intends to place additional information on its website and hold informational sessions on the *Final Rule*.

DATES: Effective September 27, 2021. See **SUPPLEMENTARY INFORMATION** for further information on relevant dates for the annual inquiry service list.

FOR FURTHER INFORMATION CONTACT: Any questions related to the annual inquiry service list should be submitted to the APO/Dockets Unit (Attention: Evangeline Keenan) at (202) 482-4920 or APOSupport@trade.gov. Electronic filing questions should be submitted to access@trade.gov. For all other questions regarding the *Final Rule*, please contact the Enforcement & Compliance Communications office (Attention: Dana Moreland) at (202) 482-0063 or ECCcommunications@trade.gov.

SUPPLEMENTARY INFORMATION:

Background

On August 13, 2020, Commerce published proposed amendments to its existing regulations, 19 CFR part 351, to strengthen and improve the administration and enforcement of the antidumping and countervailing duty

laws.¹ On September 20, 2021, Commerce published the *Final Rule*.² In the *Final Rule*, Commerce established revised regulations (19 CFR 351.225) which describe the applicable procedures and standards concerning scope inquiries and scope rulings regarding whether a product is covered by the scope of a particular antidumping or countervailing duty order. In addition, Commerce established new regulations for circumvention inquiries conducted under section 781 of the Tariff Act of 1930, as amended (the Act) (new 19 CFR 351.226).

Scope Ruling Application

Revised section 351.225(c) details the procedures and requirements for an interested party to fill out and submit a scope ruling application, and further provides that Commerce will make a scope ruling application available to the public. In accordance with revised section 351.225(d), if a completed scope ruling application is accepted, Commerce will initiate a scope inquiry.

Commerce is notifying parties that the scope ruling application may be found at <https://www.trade.gov/review-or-submit-adcvd-proceedings-documents> or https://access.trade.gov/Resources/ADCVD_Resources.aspx.

Annual Inquiry Service List

Revised § 351.225(c) and (n)(1) provide that an interested party that submits a scope ruling application must serve a copy of the application on all persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin, as described in revised section 351.225(m)(2). Revised § 351.225(n)(2) and (3) describe the procedures for the “annual inquiry service list,” discussed further below. Similarly, new § 351.226(c) and (n)(1) state that an interested party that submits a request for a circumvention inquiry must serve a copy of the request on all persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin, as described in new § 351.226(m)(2). Lastly, revised section 351.225(n)(4) and new § 351.226(n)(2) provide that once a scope or circumvention inquiry has

¹ *Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*, 85 FR 49472 (August 13, 2020) (*Proposed Rule*).

² See *Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*, 86 FR 52300 (September 20, 2021) (*Final Rule*).

been initiated, a segment-specific service list will be established.

As discussed in the *Final Rule*, Commerce is notifying parties of the initial procedures for the establishment of the annual inquiry service list for each antidumping and countervailing duty order.³ Upon publication of this document, Commerce will begin to create an annual inquiry service list for each active antidumping and countervailing duty order and suspended investigation in its online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), available at <https://access.trade.gov>. Each annual inquiry service list will be saved in ACCESS, under each case number, and under a specific segment type called “AISL-Annual Inquiry Service List.”⁴

Establishment of the Annual Inquiry Service Lists

Beginning September 27, 2021, and until October 27, 2021, an interested party may request to be added to the annual inquiry service list by submitting in ACCESS an entry of appearance in the annual inquiry service list segment of any order in which it qualifies as an interested party under 19 CFR 351.102(b)(2)(i) through (ix). Instructions on how to submit an entry of appearance are available at https://access.trade.gov/help/Rel_4_External_User_Guide.pdf. No later than November 4, 2021 (the effective date of the *Final Rule* for 19 CFR 351.225 (scope) and 19 CFR 351.226 (circumvention)), Commerce will generate an annual inquiry service list for each order and suspended investigation based on the entries of appearance submitted by the interested parties. As discussed further below, to be included in the initial creation of the annual inquiry service list, all interested parties, including petitioners and governments of foreign countries must follow these procedures and submit an initial entry of appearance.

³ See *Final Rule*, 86 FR 52300 at 52335 (stating that, after the *Final Rule*’s publication, Commerce “intends to provide additional instruction to interested parties on the procedures for the annual inquiry service list, as appropriate.”)

⁴ This segment will be combined with the ACCESS Segment Specific Information (SSI) field which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A-000-000 which was published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as “AISL-January Anniversary.” Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

Annual Updates to the Annual Inquiry Service Lists

After the initial creation of the annual inquiry service lists for all active orders and suspended investigations, Commerce will update each annual inquiry service list on an annual basis beginning January 2022. Each year during the anniversary month of an order or suspended investigation, Commerce will include in the monthly Notice of Opportunity to Request Administrative Review published in the **Federal Register** (*Opportunity Notice*), a notification to all interested parties of their opportunity to submit an entry of appearance to be placed on the annual inquiry service list for those orders included in that month’s *Opportunity Notice*. Any interested party that did not previously appear on the annual inquiry service list can submit a new entry of appearance at this time.

In accordance with 19 CFR 351.225(n)(3), with the exception of petitioners and foreign governments (discussed below), all interested parties who previously appeared on an annual inquiry service list and wish to appear on the list for the next year will need to submit an amended entry of appearance in ACCESS after the *Opportunity Notice* publishes. Commerce will change the status of all entries of appearance filed in ACCESS during the initial creation of the annual inquiry service list from “Active” to “Needs Amendment.” Each interested party may take this opportunity to make any necessary amendments (e.g., changes to client list, lead attorney or contact person) at this time. If no amendments are needed, but the interested party wishes to be added to the list for the next year, it must indicate in the electronic entry of appearance form that it is renewing its request to be added to the annual inquiry service list for the next year, and then submit it. At that time, the status will be changed to “In Progress.” When Commerce approves the amended entry of appearance, it will change the status to “Active” and add the interested party to the annual inquiry service list.

Similar to the deadlines to submit requests for administrative review set out in the *Opportunity Notice*, interested parties will have until the last day of the anniversary month to submit a new entry of appearance for the annual inquiry service list or to amend its existing entry of appearance to be included in the new annual inquiry service list. If an interested party does not amend or resubmit its existing entry of appearance, the status will be set to “Inactive,” and the interested party will

be omitted from the annual inquiry service list for the next year. No later than five business days after the last day of the anniversary month, Commerce will update the annual inquiry service lists for all orders included in the *Opportunity Notice*.

Special Instructions for Petitioners and Foreign Governments

In the *Final Rule*, Commerce stated that, “after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.”⁵ Accordingly, as stated above, petitioners and foreign governments should submit their initial entry of appearance after publication of this notice in order to appear in the first annual inquiry service list for those orders for which they qualify as an interested party. Pursuant to 19 CFR 351.225(n)(3), petitioners and foreign governments will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service. However, petitioners and foreign governments are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

Other Information

For new orders and suspended investigations whose **Federal Register** notices are published after the date of this document, Commerce will create an annual inquiry service list segment in ACCESS within five business days of publication of the notice of order or suspended investigation. Interested parties will have 30 days after the date of publication to submit an entry of appearance to be added to the new annual inquiry service list, and Commerce will finalize the annual

⁵ *Id.*, 86 FR 52300 at 52335–36 (“Commerce intends to provide additional instruction to interested parties on the procedures for the annual inquiry service list, as appropriate, with special instructions for petitioners and foreign governments. Specifically, once the petitioners and foreign governments have submitted their initial requests to be added to the first annual inquiry service list for a given proceeding, it is reasonable to automatically add them in each subsequent year to the list when the annual service list for the proceeding is updated. To be clear, the first time a petitioner or foreign government wishes to be included on an annual inquiry service list, it will be incumbent upon the petitioner or foreign government to request Commerce to include them on the list. However, after that first time, inclusion for them will be automatic. Additionally, after initial inclusion on the annual inquiry service list, it is also incumbent upon the petitioner or foreign government to notify Commerce of any changes to its information.”)

inquiry service list within five business days thereafter. As mentioned above, these new lists will be updated the next year, when the *Opportunity Notice* for the relevant anniversary month is published, as described above.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove interested parties or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website at <https://access.trade.gov>.

Parties are also reminded that the procedures detailed above only pertain to the annual inquiry service list described in revised § 351.225(n) and new § 351.226(n). There are separate procedures for segment-specific service lists for scope and circumvention inquiries. Segment-specific service lists are established and revised as parties file their entries of appearance in that segment. These procedures are detailed in revised § 351.103(d), revised § 351.225(n)(4) (scope), and new § 351.226(n)(2) (circumvention).

Informational Sessions

E&C's website at <https://www.trade.gov/2021-adcud-regulations-update> will contain additional information regarding the *Final Rule*. In addition, the website will provide information on dates and times of informational sessions regarding the *Final Rule* which Commerce intends to provide to the public, as well as information on how to register for, and participate in, those informational sessions. Whether the sessions are virtual or in person, there will be a limited number of spots available for participation. Therefore, the public should review the information set forth on the website regarding availability.

Dated: September 1, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021-19443 Filed 9-24-21; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 982 and 983

[Docket No. FR-6243-N-01]

Section 8 Housing Choice Vouchers: Revised Implementation of the HUD-Veterans Affairs Supportive Housing Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Implementation guidance.

SUMMARY: This document sets forth the policies and procedures for the administration of tenant-based and project-based Section 8 Housing Choice Voucher (HCV) rental assistance under the HUD-Veterans Affairs Supportive Housing (HUD-VASH) program administered by local public housing agencies (PHAs) that have partnered with local Veterans Affairs (VA) medical facilities or other entities as designated by the Secretary of the Department of Veteran Affairs. This document updates the definition for the term VA medical center (VAMC) to also include designated service providers (DSP). This document also includes new waivers and program flexibilities as well as additional general guidance.

DATES: The guidance is effective September 27, 2021.

FOR FURTHER INFORMATION CONTACT: Ryan Jones, Director, Housing Voucher Management and Operations Division, Department of Housing and Urban Development, 451 Seventh Street SW, Room 4216, Washington, DC 20410, telephone number 202 708-0477. (This is not a toll-free number.) Individuals with hearing or speech impediments may access this number via TTY by calling the Federal Relay during working hours at 800-877-8339. (This is a toll-free number.)

SUPPLEMENTARY INFORMATION:

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I. Background

Since 2008, HCV program funding has provided rental assistance under a supportive housing program for homeless veterans authorized by section 8(o)(19) of the United States Housing Act of 1937, 42 U.S.C. 1437f(o)(19). The HUD-VASH program combines HUD HCV rental assistance for homeless veterans with case management and clinical services provided at VA Medical Centers, Community-Based Outpatient Clinics, or through a designated service provider (DSP) as approved by the VA Secretary (herein referred to generally as VAMC or DSP). Through the HUD-VASH program, HUD and VA increase access to affordable housing for homeless veterans and provide the support necessary to obtain and maintain permanent housing in the community.

Based on a review of existing permanent supportive housing (PSH) models, typical acuity levels of veterans in the program, and the availability of providers within VAMCs and in the community who can augment care provided by HUD-VASH case managers, the Secretaries of HUD and VA jointly determined that the appropriate caseload ratio in HUD-VASH is a weighted average of 25 veterans per case manager. However, actual caseload sizes can vary considerably, based primarily on the needs of the veterans being served. Veterans in HUD-VASH are weighted based on their stage in the program, with higher weightings applied to veterans in more intensive stages of the program, and lower weightings applied to those who have stabilized. These weightings and target caseload ratios ensure that all veterans in receipt of a HUD-VASH voucher are seen as needed by their case manager.

The initiative known as the HUD-VASH program was authorized pursuant to Division K, Title II, of The Consolidated Appropriations Act, 2008 (Pub. L. 110-161) ("2008 Appropriation Act") enacted on December 26, 2007 (see proviso (7) under the heading "Tenant-Based Rental Assistance"). All Congressional Appropriations Acts since 2008 have continued to authorize this program. Therefore, the implementation requirements will remain in effect until the HUD-VASH program is no longer authorized by Congress or the authorization requirements change.

The Appropriations Acts have required HUD to “make such funding available, notwithstanding section 204 (competition provision) of this title, to PHAs that partner with eligible VAMCs or other entities as designated by the Secretary of the Department of Veterans Affairs, based on geographical need for such assistance as identified by the Secretary of the Department of Veterans Affairs, PHA administrative performance, and other factors as specified by the Secretary of Housing and Urban Development in consultation with the Secretary of the Department of Veterans Affairs.”

Based on this language, the allocation of HUD–VASH vouchers have been a collaborative, data-driven effort conducted by HUD and the VA. The HUD–VASH allocation formula relies on several pieces of data which include HUD’s point-in-time data submitted by Continuums of Care and VA data on contacts with homeless veterans. PHA and VA performance is also taken into consideration.

Additional information on program requirements and procedures may be found on the HUD–VASH website at HUD–VASH website.

II. Special Rules for the HUD–VASH Voucher Program

This section sets forth the design features of the HUD–VASH program, including family eligibility, portability, case management, and the turnover of these vouchers. This document replaces the special rules published in the **Federal Register** on March 23, 2012 (77 FR 17086). The FY2008–2021 Appropriations Acts stated “that the Secretary of Housing and Urban Development (in consultation with the Secretary of the Department of Veterans Affairs) may waive, or specify alternative requirements for any provision of any statute or regulation that the Secretary of Housing and Urban Development administers in connection with the use of funds made available under this paragraph (except for requirements related to fair housing, nondiscrimination, labor standards, and the environment) upon a finding by the Secretary that any such waivers or alternative requirements are necessary for the effective delivery and administration of such voucher assistance: *Provided further*, that assistance made available under this paragraph shall continue to remain available for homeless veterans upon turnover.”

This document outlines below the waivers or alternative requirements determined by the Secretary to be necessary for the effective delivery and

administration of the HUD–VASH program. These waivers or alternative requirements are exceptions to the normal HCV requirements, which otherwise govern the provision of HUD–VASH assistance. In addition, a PHA may request additional statutory or regulatory waivers that it determines are necessary for the effective delivery and administration of the program. These requests may be submitted to the Secretary for review and decision through the Assistant Secretary for Public and Indian Housing through the regular waiver process.

HUD–VASH vouchers under this part are administered in accordance with the HCV tenant-based and project-based rental assistance regulations set forth at 24 CFR part 982 and 983, respectively. In both programs, the PHA pays monthly rental subsidies so that eligible families can afford decent, safe, and sanitary housing, secure from threats of danger, harm, or loss. HUD provides housing assistance funds to the PHA, as well as funds for PHA administration of the program.

Under the HCV program, families select rent units that meet program housing quality standards (HQS). If the PHA approves a family’s unit and tenancy, the PHA contracts with the property owner to make monthly subsidy payments (housing assistance payments) directly to the owner on behalf of the family. The family enters a lease with the owner and pays its share of the rent to the owner in accordance with the lease. Under the HCV tenant-based voucher (TBV) program, the housing assistance payments (HAP) contract between the PHA and the owner covers only a single unit and a specific assisted family. If the family moves out of the leased unit, the HAP contract with the owner terminates. The family may generally move to another unit with continued assistance so long as the family is complying with program requirements.

Under the project-based voucher (PBV) program, families occupy units under a PBV HAP contract. Generally, there are multiple units under the PBV HAP contract. In many cases supportive services are provided on-site. All the PBV requirements in 24 CFR part 983 apply except where waived as described below.

Unless expressly noted below, all regulatory requirements and HUD directives regarding the HCV TBV and PBV programs are applicable to HUD–VASH vouchers, including the use of all HUD-required contracts and other forms. The PHA’s local discretionary policies adopted in the PHA’s written administrative plan apply to HUD–

VASH vouchers unless such local policy conflicts with the requirements of the HUD–VASH vouchers outlined below.

PHAs are required to maintain records that allow for the easy identification of families receiving HUD–VASH vouchers. PHAs must identify these families in the Information Management System/Public and Indian Housing Information Center (IMS/PIC). This record-keeping will help ensure that, in accordance with appropriations renewal language, HUD–VASH vouchers that are in use will remain available for homeless veterans upon turnover.

The alternative requirements established in this Notice apply to all PHAs that administer HUD–VASH vouchers, including those that have not received an allocation of HUD–VASH vouchers, but administer these vouchers as a receiving PHA under the portability feature of the HCV program.

The new waivers and program flexibilities include: (1) New authorization allowing a PHA to act in the role of the VAMC or DSPs for the purposes of family selection in cases where the PHA has been previously approved for this authority (section II.a.); (2) new allowance for a PHA and owner to agree to amend a PBV HAP contract to re-designate a regular PBV unit as a unit specifically designated for HUD–VASH families (section II.k); (3) new authorization for PHAs to apply separate payment standards for HUD–VASH families without additional HUD approval (section II.o.); and (4) new requirement that PHAs must allow Special Housing Types for HUD–VASH (section II.p.).

The updates made to existing requirements include: (1) Allowing PHAs to house HUD–VASH veterans referred by the VA in a project-based voucher unit without selecting from the PHA’s waiting lists or applying local preferences (section II.a); (2) additional explanation regarding the process for portability moves for victims of domestic violence, dating violence, sexual assault, and stalking (section II.f); (3) additional details regarding case management requirements from the VAMC or DSP (section II.g); (4) explanation that, in the case of a family break-up, the HUD–VASH assistance must stay with the HUD–VASH veteran; however, in the case of domestic violence, dating violence, sexual assault, or stalking in which the HUD–VASH veteran is the perpetrator, the victim must continue to be assisted (section II.h.); (5) explanation that a Moving to Work (MTW) PHA can apply their approved MTW provisions to their HUD–VASH program with approval from HUD’s Housing Choice Voucher

office (section II.j.); (6) explanation regarding the application of HUD–VASH waivers and flexibilities to HUD–VASH PBV (section II.k.); (7) explanation of HUD–VASH PBV exceptions under the Housing Opportunities Through Modernization Act (HOTMA) (section II.k.); (8) explanation that when a HUD–VASH family is eligible to move from its PBV unit the family must be able to move with a HUD–VASH tenant-based voucher (section II.k.); and (9) additional explanation of the HUD–VASH reallocation process through voluntary moves between PHAs and voucher recapture for future reallocation (section II.m.).

This document does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition or new construction, or establish, revise or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this document is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

a. Family Eligibility and Selection

HUD–VASH eligible families consist of homeless veterans and their families. The Appropriations Acts have provided for statutory or regulatory waivers or alternative requirements upon a finding by the Secretary that such waivers or alternatives are necessary for the effective administration and delivery of voucher assistance (except for requirements related to fair housing, nondiscrimination, labor standards, and the environment). The December 17, 2007, Explanatory Statement for the 2008 Appropriation Act provides, “The Appropriations Committees expect that these vouchers will be made available to all homeless veterans, including recently returning veterans.”¹ Section 8(o)(19) of the United States Housing Act of 1937 (USHA of 1937), which requires homeless veterans to have chronic mental illnesses or chronic substance use disorders with required treatment of these disorders as a condition of receipt of HUD–VASH assistance, is waived.

By agreeing to administer the HUD–VASH program, the PHA is relinquishing its authority to determine the eligibility of families in accordance with regular HCV program rules and

PHA policies with the exceptions of income eligibility and lifetime sex offender status. Specifically, under the HUD–VASH program, PHAs will not have the authority to screen any potentially eligible family members or deny assistance for any grounds permitted under 24 CFR 982.552 (broad denial for violations of HCV program requirements) and 982.553 (specific denial for criminal activity and alcohol abusers), with one exception. PHAs will still be required to prohibit admission if any member of the household is subject to a lifetime registration requirement under a state sex offender registration program. However, unless the family member that is subject to lifetime registration under a state sex offender registration program is the homeless veteran (which would result in denial of admission for the family), the remaining family member/s may be served if the family agrees to remove the sex offender from its family composition.

Accordingly, HUD is exercising its authority to waive 42 U.S.C. 1437d(s); 42 U.S.C. 13661(a), (b), and (c); and 24 CFR 982.552 and 982.553 regarding the denial of admission, except for 982.553(a)(2)(i), which requires denial of admission to certain registered sex offenders. These provisions also apply to PBV assistance.

Eligibility determination and veteran selection is done by the VAMC, DSP, or the PHA, as described later in this section. In the case of the VAMC or DSP, HUD–VASH eligible families are referred to the partnering PHA for the issuance of a voucher or selection for a PBV unit. As stated above, the PHA must accept these referrals, and written documentation of these referrals must be maintained in the tenant file at the PHA.

PHAs are not authorized to maintain a waiting list or apply local preferences for the HUD–VASH program. Instead, VA case managers refer HUD–VASH eligible families to the PHA for the issuance of a HUD–VASH voucher or project-based assistance. If a HUD–VASH-eligible family is referred and there is an available PBV unit that is not exclusively made available to HUD–VASH families, the PHA may also offer to refer the family to the owner for occupancy of that unit if allowable under the selection policy applicable to that project, and the owner and PHA may amend the PBV HAP contract to designate the PBV unit as a HUD–VASH PBV unit. Accordingly, sections 8(o)(6)(A) and (B) and 8(o)(13)(f) of the USHA of 1937, 42 U.S.C. 1437f(o)(6)(A) and (B) and (o)(13)(f), regarding preferences, have been waived to provide for the effective administration

of the program. In addition, 24 CFR 982.202, 982.204, 982.207, and 983.251 relating to applicant selection from the waiting list and local preferences, are also waived. Section 983.251(a)(4), which disallows renting to relatives except when it may be necessary as a reasonable accommodation, is not waived. Note that 24 CFR 982.202(b)(3) (Family characteristics); 24 CFR 982.202(d) (Admission policy); and 24 CFR 983.251(a)(3) (VAWA applies to admission to the project-based voucher program) continue to apply. Sections 982.203, 982.205, and 982.206 regarding special admissions, cross-listing of the waiting list, and opening and closing the waiting list do not apply to the HUD–VASH program.

The VA may approve a PHA with unleased HUD–VASH vouchers as a DSP for the purposes of veteran selection and intake. This DSP approval allows a PHA to issue a HUD–VASH voucher to a veteran without a referral from the VA. The PHA is responsible for determining the veteran is eligible for VA HUD–VASH case management. The PHA must refer the veteran to the VA for case management and must provide temporary case management until the VAMC has completed intake of the veteran. PHAs approved under this authority must ensure that while using unleased HUD–VASH vouchers, they maintain sufficient HUD–VASH vouchers available to immediately issue a HUD–VASH voucher to veterans referred by the VA. HUD and the VA will publish further guidance on the requirements for a PHA to be approved and additional details necessary for PHAs to implement this provision. Until such guidance is issued, PHAs may not be approved as DSPs.

Regarding verifying Social Security Numbers (SSN) for homeless veterans and their family members, an original document issued by a federal or state government agency which contains the name of the individual and the SSN of the individual along with other unique identifying information of the individual is acceptable in accordance with 24 CFR 5.216(g). In the case of the homeless veteran, the PHA must accept the *Certificate of Release or Discharge from Active Duty* (DD–214) or the VA-verified *Application for Health Benefits* (10–10EZ) as verification of SSN and cannot require the veteran to provide an SSN card. These documents must also be accepted for proof of age purposes in lieu of birth certificates or other PHA-required documentation. Please note that veterans are also issued photo identification cards by the VA. If such identification is required by the PHA, these cards must be accepted by the

¹ See, 153 Cong. Rec. H16514 (daily ed., Dec. 17, 2007), <https://www.congress.gov/crc/rec/2007/12/17/CREC-2007-12-17-pt3-PgH16381.pdf>.

PHA in lieu of another type of government-issued photo identification. These cards may also be used to verify SSNs and date of birth.

When adding a family member after the HUD-VASH family is admitted to the program, the rules of § 982.551(h)(2) apply. Other than the birth, adoption, or court-awarded custody of a child, the PHA must approve additional family members and may apply its regular screening criteria in doing so.

*** Civil rights requirements cannot be waived. The HUD-VASH program is administered in accordance with applicable civil rights and fair housing requirements. These include applicable authorities under 24 CFR 5.105(a) and 24 CFR 982.53 including, but not limited to, the Fair Housing Act, Section 504 of the Rehabilitation Act of 1973, Title VI of the Civil Rights Act of 1964, the Age Discrimination Act, the Americans with Disabilities Act, and HUD's Equal Access Rule.²

When HUD-VASH applicants or recipients include veterans with disabilities or family members with disabilities, HUD's reasonable accommodation requirements apply. These standards require PHAs to make a reasonable adjustment to rules, policies, practices, and procedures when it may be necessary to enable an applicant or resident with a disability to have an equal opportunity to use and enjoy a dwelling, the common areas of a dwelling, or participate in or access a recipient's programs and activities. These standards extend to various aspects of program implementation, including, for example, denial or termination of assistance, initial search term of the HCV, initial lease term, and informal reviews and hearings. In the case of project-based assistance, this also includes providing structural changes to a unit or public or common use area when they may be needed as a reasonable accommodation for an applicant or participant or their household members with a disability. Other obligations include, for example, effective communication with persons with disabilities, physical accessibility requirements, and overall nondiscrimination in the administration of the program.*

b. Income Eligibility

The PHA must determine income eligibility for HUD-VASH families in accordance with 24 CFR 982.201.

Income targeting requirements of section 16(b) of the USHA of 1937, as well as 24 CFR 982.201(b)(2), do not apply for HUD-VASH families so that participating PHAs can effectively serve the eligible population specified in the Appropriations Acts; that is, homeless veterans, who may be at a variety of income levels, including low-income. The PHA may, however, choose to include the admission of extremely low-income HUD-VASH families in its income targeting numbers for the fiscal year in which these families are admitted. In conformance with normal program rules, PHAs may not deny admission to a family with zero income and must consider hardship circumstances before charging a minimum rent in accordance with 24 CFR 5.630(b).

c. Initial Search Term of the Voucher

Recognizing the challenges that HUD-VASH participants may face with their housing search, HUD-VASH vouchers must have an initial search term of at least 120 days. Therefore, 24 CFR 982.303(a), which states that the initial search term must be at least 60 days, shall not apply, since the initial term must be at least 120 days. Any extensions, suspensions, and progress reports will remain under the policies in the PHA's administrative plan but will apply after the minimum 120-day initial search term. Extensions of search terms may also be needed as a reasonable accommodation for a household with a member with a disability, such as for example, due to the difficulty in finding a unit that meets one's disability-related needs, e.g., physically accessible unit, unit near accessible transportation, unit near medical or other facilities.

d. Initial Lease Term

Under the HCV program, voucher participants must enter an initial lease with the owner for at least one year, unless a shorter term would improve housing opportunities for the tenant and the shorter term is a prevailing market practice. To provide a greater range of housing opportunities for HUD-VASH voucher holders, initial leases may be less than 12 months; therefore, both section 8(o)(7)(A) of the USHA of 1937, 42 U.S.C. 1437f(o)(7)(A), and 24 CFR 982.309(a)(2)(ii) are waived. Note that this waiver does not apply to PBVs.

e. Ineligible Housing

HUD-VASH families will be permitted to live on the grounds of a VA facility in units developed to house homeless veterans. This applies to both tenant-based assistance and PBV. Therefore, 24 CFR 982.352(a)(5) and

982.53(a)(2), which prohibit units on the physical grounds of a medical, mental, or similar public or private institution, are waived for that purpose only.

f. Mobility and Portability of HUD-VASH Vouchers

An eligible family issued a HUD-VASH voucher must receive case management services provided by the partnering VAMC or DSP. Therefore, special mobility and portability procedures must be established. HUD-VASH participant families may reside only in those jurisdictional areas that are accessible to case management services as determined by the VAMC or DSP. Since the VAMC or DSP will be identifying homeless veterans eligible to participate in the HUD-VASH program, section 8(r)(1)(B)(i) of the USHA of 1937, 42 U.S.C. 1437f(r)(1)(B)(i), which restricts portability in cases where the family did not reside in the jurisdiction of the PHA at the time of application for HCV assistance, and 24 CFR 982.353(a), (b), and (c), which affects where a family can lease a unit with HCV assistance, do not apply. HUD may publish PIH notices from time to time to further explain portability requirements under the HUD-VASH program.

(1) Portability Moves Within Same Catchment Area (or Area of Operation) Where Case Management Is Provided by the Initial PHA's Partnering VAMC or DSP

If the family initially leases up, or moves, under portability provisions, but the initial PHA's partnering VAMC or DSP will still be able to provide the necessary case management services due to the family's proximity to the partnering VAMC or DSP, the receiving PHA must process the move in accordance with the portability procedures of 24 CFR 982.355. However, since the initial PHA must maintain records on all HUD-VASH families receiving case management services from its partnering VAMC or DSP, receiving PHAs without a HUD-VASH program must bill the initial PHA. Therefore, 24 CFR 982.355(d), which gives the receiving PHA the option to absorb the family into its own HCV program or bill the initial PHA, is not applicable.

(2) Portability Moves Within Same Catchment Area Where Both PHAs Have Received HUD-VASH Vouchers

The receiving PHA may bill the initial PHA or absorb the family into its own HUD-VASH program if the VAMC or DSP providing the initial case management agrees to the absorption by the receiving PHA and the transfer of

² See 24 CFR 5.105(a); See also, U.S. Department of Housing and Urban Development, Fair Housing Rights and Obligations, https://www.hud.gov/program_offices/fair_housing_equal_opp/fair_housing_rights_and_obligations (last visited Sept. 17, 2021).

case management. The absorption will also entail the availability of a HUD–VASH voucher and case management provision by the receiving PHA’s partnering VAMC or DSP.

(3) Portability Moves Where Receiving PHA Is Beyond Catchment Area

If a family wants to move to another jurisdiction where it will not be possible for the initial PHA’s partnering VAMC or DSP to provide case management services, the VAMC or DSP must first determine that the HUD–VASH family could be served by another VAMC or DSP that is participating in this program, and the receiving PHA must have a HUD–VASH voucher available for this family. In these cases, the family must be absorbed by the receiving PHA either as a new admission (upon initial participation in the HUD–VASH program) or as a portability move-in (after an initial leasing in the initial PHA’s jurisdiction). Upon absorption, the initial PHA’s HUD–VASH voucher will be available to lease to a new HUD–VASH eligible family, as determined by the partnering VAMC or DSP, and the absorbed family will count toward the number of HUD–VASH slots awarded to the receiving PHA.

When the receiving PHA completes the *Family Report* (HUD–50058) under the scenario described above, the action type that must be recorded on line 2a is “1” for a new admission (a family that is new to the HCV program) or “4” for a portability move-in (a family that was previously leased up in the jurisdiction of the initial PHA). Whether the family is a new admission or portability move-in, in section 12 of the HUD–50058, line 12d is always marked “Y.” In cases of portability where families move out of the catchment area of the initial PHA, 12e must be 0 since the family must be absorbed, and 12f must be left blank.

(4) Portability Moves Where Receiving PHA Is Beyond Catchment Area for Victims of Domestic Violence, Dating Violence, Sexual Assault, and Stalking

Veterans who request to port beyond the catchment area of the VAMC or DSP where they are receiving case management to protect the health or safety of a person who is or has been the victim of domestic violence, dating violence, sexual assault, or stalking, and who reasonably believes him- or herself to be threatened with imminent harm from further violence by remaining in the dwelling unit (or any family member has been the victim of a sexual assault that occurred on the premises during the 90-calendar-day period preceding the family’s move or request to move), may port prior to receiving approval

from the receiving VAMC or DSP. The initial PHA must follow its emergency transfer plan as described in 24 CFR 5.2005(e). PHAs may require verbal self-certification or a written request from a participant seeking a move beyond the catchment area of the VAMC or DSP.

The verbal self-certification or written request must include either, a statement expressing why the participant reasonably believes that there is a threat of imminent harm from further violence if the participant were to remain in the same dwelling unit assisted under the PHA; or a statement that the tenant was a sexual assault victim and that sexual assault occurred on the premises during the 90-day period preceding the participant’s request for the move. The veteran escaping violence must be admitted to the VAMC or DSP’s caseload. The participant must still port to a PHA that has a HUD–VASH program; if the receiving PHA does not have a HUD–VASH voucher available to lease, they may bill the initial PHA until a HUD–VASH voucher is available, at which point the porting veteran must be absorbed into the receiving PHA’s program.

(5) Portability Moves when Case Management Is No Longer Required

If the family no longer requires case management, as determined by the VAMC or DSP, there are no portability restrictions. PHAs must follow the regulatory requirements for portability found at 24 CFR 982.355. When completing the HUD–50058, the family will continue to be coded “VASH” on line 2n unless the family has been moved to a regular voucher, in which case the code in 2n would be left blank.

g. Case Management Requirements

The VAMC or DSP’s responsibilities include: (1) The screening of homeless veterans to determine whether they meet the HUD–VASH program participation criteria established by the VA national office; (2) assisting veterans with the PHA application and assisting the veteran family with obtaining needed PHA documentation to ensure rapid voucher issuance; (3) referrals of homeless veterans to the PHA; (4) providing case management and supportive services to potential HUD–VASH program participants, as needed, prior to PHA issuance of rental vouchers; (5) providing housing search assistance to HUD–VASH participants with rental vouchers; (6) identifying the social service and medical needs of HUD–VASH participants and providing, or ensuring the provision of, regular ongoing case management, outpatient health services, hospitalization, and

other supportive services, as needed, throughout this initiative; and (7) maintaining records and providing information for evaluation purposes, as required by HUD and the VA.

As a condition of HCV rental assistance, both tenant-based assistance and PBV, a HUD–VASH eligible veteran must receive the case management services noted above, as needed, directly from or arranged by, the VAMC or DSP. The VAMC or DSP, in consultation with the veteran, is responsible for determining if case management is required and if the case management requirement is satisfied.

If a veteran no longer requires case management, but maintains their HUD–VASH voucher assistance, the VAMC or DSP will maintain contact with the veteran family to provide support and planning assistance with the recertification and reinspection process. The VAMC or DSP case manager will remain available to provide support to the veteran family, as needed.

h. Termination of Assistance

There are two alternative requirements for termination of assistance for HUD–VASH participants. As detailed above, HUD–VASH voucher assistance is contingent upon participation in case management, as required by the VAMC or DSP. If the VAMC or DSP has determined that a veteran is not participating in required case management, without good cause, the PHA must terminate the family from the HUD–VASH program. However, a VAMC or DSP determination that the veteran does not require or no longer requires case management is not grounds for termination of voucher or PBV assistance. In such case, and at its option, the PHA may offer the family continued assistance through one of its regular vouchers, to free up the HUD–VASH voucher for another eligible family referred by the VAMC or DSP. If the PHA has no voucher to offer, the family will retain its HUD–VASH voucher, or PBV unit, until such time as the PHA has an available voucher for the family. If the family no longer requires case management, there are no portability restrictions. Normal portability rules apply.

Second, PHAs may terminate a family evicted from housing assisted under the program for a serious violation of the lease, but they are not required to do so. As such, the regulation at 24 CFR 982.552(b)(2) is amended to state, “The PHA may terminate program assistance for a family evicted from housing assisted under the program for serious violation of the lease.” Prior to terminating HUD–VASH participants,

HUD strongly encourages PHAs to exercise their discretion under 24 CFR 982.552(c)(2) and consider all relevant circumstances of the specific case, as well as including the role of the case manager and the impact that ongoing case management services can have on mitigating the conditions that led to the potential termination, prior to determining whether to terminate assistance. PHAs also must grant reasonable accommodations for persons with disabilities in accordance with 24 CFR part 8. In addition, a HUD-VASH participant family must not be terminated after admission, for a circumstance or activity that occurred before admission and was known to the PHA but could not be considered at the time of admission due to the HUD-VASH Operating Requirements. The PHA can only terminate the family's assistance for program violations that occur after the family's admission to the voucher program.

Generally, in the case of a family break-up, the HUD-VASH assistance must stay with the HUD-VASH veteran. However, in the case of domestic violence, dating violence, sexual assault, or stalking, in which the HUD-VASH veteran is the perpetrator, the victim must continue to be assisted. Upon termination of the perpetrator's HUD-VASH voucher due to the perpetrator's acts of domestic violence, dating violence, sexual assault, or stalking, the victim must be given a regular HCV if one is available, and the perpetrator's HUD-VASH voucher must be used to serve another eligible veteran family. If a regular HCV is not available for the victim, the perpetrator must be terminated from assistance, and the victim will continue to utilize the HUD-VASH voucher.

i. Turnover of HUD-VASH Vouchers

In accordance with the Appropriations Acts, upon turnover, HUD-VASH vouchers must be issued to homeless veteran families as identified by the VAMC or DSP, as noted above.

j. Moving-to-Work (MTW) Agencies

HUD-VASH vouchers may be administered in accordance with flexibilities approved under PHA's Standard MTW Agreement or MTW Operations Notice with approval from HUD's Housing Choice Voucher office. PHAs must submit a request through their local field office to operate HUD-VASH in accordance with approved MTW flexibilities. Requests will be approved provided the flexibilities do not conflict with the stated HUD-VASH program requirements. However, these vouchers are never eligible for MTW

fungibility. HUD-VASH vouchers must be reported in the IMS/PIC system on either the regular HUD-50058 or HUD-MTW 50058 for vouchers under the agency's MTW Agreement.

k. Project-Based Assistance

Section 8(o)(13)(D) of the USHA of 1937 (42 U.S.C. 1437(o)(13)(D)), as amended by Section 106(a)(3) of the Housing Opportunities Through Modernization Act (HOTMA) (Pub. L. 114-201, 130 Stat. 782), is waived for HUD-VASH vouchers so that all units exclusively made available to HUD-VASH families in a PBV project are exempted from the PBV income-mixing requirements (project cap). The project cap refers to the number of units in a project that may receive PBV assistance and is generally the higher of 25 units or 25 percent of units in the project. Units exclusively made available to HUD-VASH families are excluded from (do not count against) this PBV project cap. Additionally, HUD-VASH supportive services only need to be provided to all HUD-VASH families in the project, not all families receiving PBV assistance in the project. If a HUD-VASH family does not require or no longer requires case management, the unit continues to count as an excepted PBV unit for as long as the family resides in that unit. Likewise, Section 8(o)(13)(B) of the USHA of 1937, 42 U.S.C. 1437f(o)(13)(B)), as amended by Section 106(a)(2) of HOTMA, is waived for HUD-VASH vouchers so that HUD-VASH units made available under a competitive PIH notice for HUD-VASH PBV units, are exempt from the PBV program limitation. This exception only applies to HUD-VASH PBV vouchers awarded through the HUD-VASH PBV set-aside process. All other HUD-VASH vouchers that the PHA opts to project-base, are still subject to the PBV program limitation.

Pursuant to the HUD-VASH case management and termination requirements, a HUD-VASH family's PBV assistance must be terminated for failure to participate in case management as required by the VAMC or DSP. Upon notification by the VAMC or DSP of the family's failure to participate, without good cause, in case management, the PHA must provide the family a reasonable time period (as established by the PHA) to vacate the unit. The PHA must terminate assistance to the family at the earlier of (1) the time the family vacates or (2) the expiration of the reasonable time period given to vacate (the lease terminates at the same time as termination of assistance per 24 CFR 983.256(f)(3)(v)). If the family fails to vacate the unit

within the established time, the owner may evict the family. If the owner does not evict the family, the PHA must remove the unit from the HAP contract or amend the HAP contract to substitute a different unit in the project if the project is partially assisted. A PHA may add the removed unit to the HAP contract after the ineligible family vacates the property.

If a HUD-VASH family is eligible to move from its PBV unit and there is no HUD-VASH tenant-based voucher available at the time the family requests to move, the PHA may require a family that still requires case management to wait for a HUD-VASH tenant-based voucher for a period not to exceed 180 days. If a HUD-VASH tenant-based voucher is still not available after that time period, the family must be allowed to move with its HUD-VASH voucher. Alternatively, the PHA may allow the family to move with its HUD-VASH voucher without having to meet this 180-day waiting period. In either case, the PHA may either replace the assistance in the PBV unit with one of its regular vouchers if the unit is eligible for a regular PBV (for instance, so long as the unit is not on the grounds of a medical facility and so long as the unit is eligible under the PHA's program and project caps) or the PHA and owner may agree to temporarily remove the unit from the HAP contract. If a HUD-VASH veteran has been determined to no longer require case management, the PHA must allow the family to move with the first available tenant-based voucher if no HUD-VASH voucher is immediately available and cannot require the family to wait for a HUD-VASH voucher to become available.

Under HOTMA, PHAs no longer need authorization from HUD to convert tenant-based HUD-VASH vouchers to project-based HUD-VASH vouchers. However, PHAs must consult with the partnering VAMC or DSP to ensure approval of the project. PHAs and the partnering VAMC or DSP are expected to communicate regarding the PBV planning and development. PHAs may project-base HUD-VASH vouchers in projects alongside other PBV units (the other PBV units must be attached in accordance with PBV requirements) and may execute a single HAP contract covering both the HUD-VASH PBVs and the other PBVs. In the description of units in Exhibit A of the HAP contract, PHAs must indicate the number of units that will be exclusively made available to HUD-VASH families. The PHA must refer only HUD-VASH families to PBV units exclusively made available to HUD-VASH families and to PBV units funded through a HUD-

VASH PBV set-aside award. The PHA and owner may agree to amend a PBV HAP contract to re-designate a regular PBV unit as a unit specifically designated for HUD-VASH families, so long as the PHA first consults with the VAMC or DSP. Additionally, the PHA and owner may agree to amend a PBV HAP contract to re-designate a unit specifically designated for HUD-VASH families as a regular PBV unit, so long as the unit is not funded through a HUD-VASH PBV set-aside award and is eligible for a regular PBV (for instance, the unit is not on the grounds of a medical facility and the unit is eligible under the PHA's program and project caps).

PBV project selection for HUD-VASH must follow all regular project selection regulations.

l. Section Eight Management Assessment Program (SEMAP)

HUD-VASH vouchers will remain excluded from the SEMAP leasing indicator. Therefore, 24 CFR 985.3(n)(1)(i) and (ii) are still waived. During a HUD-VASH PHA's calendar year, the prorated budget authority available for HUD-VASH vouchers and the units associated with that budget authority will be excluded from the denominators for both units leased, and dollars expended.

m. Reallocation of HUD-VASH Vouchers

Under the Appropriation Acts, Congress has directed VA and HUD to collaboratively allocate HUD-VASH vouchers based on current geographical need for such assistance. In recognition that there may be changes and shifts in the population of homeless veterans over time, it may become necessary for the VA and HUD to jointly reallocate HUD-VASH vouchers to better address the current needs of the homeless veteran population. This reallocation may be done in one of two ways. If there is continued need at the VAMC or DSP, HUD-VASH vouchers may be voluntarily moved between PHAs administering HUD-VASH programs within the same VAMC or DSP catchment area. Alternatively, if it has been determined that a VAMC or DSP no longer has sufficient need and will not be able to utilize their available HUD-VASH vouchers, HUD and VA may choose to jointly recapture HUD-VASH vouchers from the VAMC or DSP and any partnering PHA(s). Recaptured vouchers, and any associated funding, will be reallocated through a national allocation process, to areas with current need. HUD will issue additional PHA guidance on both HUD-VASH voucher

voluntary moves within a VAMC or DSP and the HUD-VASH recapture processes.

n. HQS Inspections

To expedite the leasing process for tenant-based HUD-VASH, PHAs may pre-inspect available units that veterans may be interested in leasing to maintain a pool of eligible units. If a HUD-VASH family selects a unit that passed a HQS inspection (without intervening occupancy) within 45 days of the date of the Request for Tenancy Approval (form HUD-52517), the unit may be approved as long as it meets all other conditions under 24 CFR 982.305. As required by 24 CFR 982.353(e), a PHA is prohibited from directly or indirectly reducing the family's opportunity to select among all available units. All regulatory requirements pertaining to HQS found at 24 CFR 982.401 apply to HUD-VASH.

o. Exception Payment Standards

Many housing markets with a high need for HUD-VASH are very competitive with a shortage of affordable rental units. In addition, landlords may be reluctant to rent to homeless individuals due to poor credit history or other issues. To assist HUD-VASH participants in finding affordable housing, especially in competitive markets, HUD is waiving 24 CFR 982.503(a)(3) to allow a PHA to establish a HUD-VASH exception payment standard. Without this waiver, a PHA is required to establish a single payment standard amount for each unit size. Additionally, 982.503(b)(iii) is waived so that PHAs may go up to, but no higher than 120 percent of the published metropolitan area-wide FMRs or Small Area FMRs (based on which FMRs the PHA is applying) specifically for HUD-VASH families. A PHA that wants to establish a HUD-VASH exception payment standard over 120 percent must still request a waiver from HUD through the regular waiver process outlined in notice PIH 2018-16, or any successor notices. Exception payment standards implemented by the PHA under this Section also apply in determining rents for PBV projects with units exclusively made available to HUD-VASH families (see 24 CFR 983.301).

p. Special Housing Types

Special housing types can be particularly useful to HUD-VASH clients, as it can increase the availability of housing, and for some veterans, can be a better housing environment than a single-family unit. As such, PHAs must permit HUD-VASH clients to use the

following special housing types for tenant-based HUD-VASH assistance, regardless of whether these types are permitted in their administrative plan for other families: single room occupancy (SRO); congregate housing; group home; shared housing; and cooperative housing. Regulations for these housing types can be found at 24 CFR part 982, subpart M.

Consistent with the regulations, HUD-VASH PBV can never be applied to shared housing.

III. Reporting Requirements

The VASH code was established for use on line 2n of the Family Report (form HUD-50058) or 2p of the MTW 50058, to indicate if the family participates in a special program. The information collection requested on both Family Reports has been approved by the Office of Management and Budget (OMB) and given OMB control number 2577-0083. No person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), unless that collection displays a currently valid OMB control number. This code must remain on the HUD-50058 and MTW 50058 for the duration of the HUD-VASH family's participation in the program. The PHA that administers the HUD-VASH voucher on behalf of the family (regardless of whether the PHA has received an allocation of HUD-VASH vouchers) must enter and maintain this code on the HUD-50058 or MTW 50058.

Data will also be captured in the Voucher Management System (VMS) on monthly leasing and expenditures for HUD-VASH vouchers.

For any additional systems reporting requirements that may be established, HUD will provide further guidance.

Dominique Blom,

General Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 2021-20734 Filed 9-24-21; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 117**

[Docket No. USCG–2019–0824]

RIN 1625–AA09

Drawbridge Operation Regulation; Milwaukee, Menomonee, and Kinnickinnic Rivers and Burnham Canals, Milwaukee, WI**AGENCY:** Coast Guard, Department of Homeland Security (DHS).**ACTION:** Final rule.

SUMMARY: The Coast Guard is altering the operating schedules of the bridges over the Milwaukee, Menomonee, and Kinnickinnic Rivers and Burnham Canals. The City of Milwaukee requested the regulations to be reviewed and updated to allow for a more balanced flow of maritime and land based transportation.

DATES: This rule is effective October 27, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>. Type USCG–2019–0824 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 Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216–902–6085, email Lee.D.Soule@uscg.mil.

SUPPLEMENTARY INFORMATION:**I. Table of Abbreviations**

CFR Code of Federal Regulations
 DHS Department of Homeland Security
 FR Federal Register
 IGLD85 International Great Lakes Datum of 1985
 LWD Low Water Datum based on IGLD85
 NPRM Notice of proposed rulemaking (Advance, Supplemental)
 OMB Office of Management and Budget
 PVA Passenger Vessel Association
 § Section
 U.S.C. United States Code

II. Background Information and Regulatory History

On November 26, 2019, we published in the **Federal Register** (84 FR 65045) an advanced notice of proposed rulemaking request for comments and on March 9, 2020, we published in the **Federal Register** (85 FR 13517) notice of temporary deviation from regulations; request for comments that allowed the

city to test the new schedule and allow residents to comment all summer. The comments we received from these documents led us to publish in the **Federal Register** (86 FR 20344, April 19, 2021) a notice of proposed rulemaking. Several comments were directed at the operation of the Canadian Pacific Railroad Bridge, mile 1.05, over the Menomonee River. Most of the comments were complaints filed on Coast Guard Delay reports that claims the Canadian Pacific Railroad Bridge, mile 1.05, over the Menomonee River, did, on August 6, 2020, on or about noon that day fail to respond to signals for opening and fail to open the bridge within the 2-hour requirement. The tender stated the request for advance notice for bridge opening was not passed on by the previous drawtender and that priority was given to working on a train and not tending to the bridge. This resulted in three large vessels stuck between bridges waiting for the railroad bridge to open for two hours and forty-five minutes past the arrival time provided by the vessels. We received a separate report that the bridge was out of service for four days, no report was given to the U.S. Coast Guard Command Center and at least one vessel was delayed for four days. We received another report that the bridge was unable to open on October 6, 2020, because the bridge supervisor directed the drawtender to a different location for the day and no other operators were available until the following day. We received a separate report on the same day of October 6, 2020, from a second vessel that was told railroad had been attempting to call in another drawtender from 4:30 a.m. to 8:19 a.m. without success and the bridge would not open for maritime traffic. On or about June 13, 2020, three sailing vessels were observed waiting at the Canadian Pacific Railroad Bridge at 3:23 p.m. and were not provided an opening until after 5:30 p.m.

The second report was a comment submitted to the [regulations.gov](https://www.regulations.gov) portal that requested the schedules to return to the original schedules citing vessels were using excessive speed to go through the river to make the new schedule. The speed limits in the harbor needs to be addressed by the agency responsible for posting the speed limits in the harbor and the author did not consider the needs of all modes of transportation involved with the decision.

On March 30, 2021, we received a report from a public vessel that the drawtender did inform the vessel that requested an opening that a new law

required the bridge to remain closed if ice was present.

Separately we discussed with residents who comments on the two hour advance notice required by some bridges, a carryover of the original 1984 regulation that mariners didn't notice before or that was not enforced locally.

Milwaukee Harbor is host to several different vessels and having a large recreational or commercial vessel station keeping between two bridges could be a danger to other vessels traveling between the bridges. The exemption prevents vessels from using excessive speed to clear the bridges before the special bridge hours go into effect and prevents vessels from endangering others waiting for the bridges to open.

After careful review of the comments received against the 50 ton proposed rule we decided that vessels with a documented capacity of 12 tons or greater could cause significant danger to life and property if trapped between two bridges and caused to station keep, especially with other vessels nearby.

We explained this is not an exclusion for documented vessels 12 tons and larger. This provision is allowing vessels of this size to complete their passage in or out of the Milwaukee Harbor. A vessel at dock or not yet in the river, would be required to wait.

Our office did engage with residents verbally over the phone on several occasions to answer questions and encouraged them to leave comments on the [regulations.gov](https://www.regulations.gov) website. Most of these engagements were with citizens that did not fully read the previous documents concerning the regulation change.

III. Legal Authority and Need for Rule

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

The Milwaukee River is approximately 104 miles long. Beginning in Fond du Lac County the river flows easterly to a low head dam just above the Humboldt Avenue Bridge at mile 3.22 in downtown Milwaukee, WI. From here the river flows south to Lake Michigan. This southerly course of the Milwaukee River divides the lakefront area from the rest of the city. The Menomonee River joins the Milwaukee River at Mile 1.01 with the Kinnickinnic River joining the Milwaukee River at Mile 0.39. 21 bridges cross the Milwaukee River from mile 0.19 to mile 3.22. In the early 20th Century, the Milwaukee River was heavily used to support the industries in and around the Great Lakes. Today, the river has been redeveloped as a tourist and recreational destination. From its

confluence with the Milwaukee River the Menomonee River flows west for 33 miles. The lower three miles of the Menomonee River is passable by vessels over 600 feet in length. Seven bridges cross the navigable portion of the Menomonee River.

The South Menomonee Canal and the Burnham Canal were both excavated during a waterways improvement project in 1864. Both man-made canals are tributaries of the Menomonee River branching just above its mouth. The South Menomonee Canal is crossed by two bridges and the Burnham Canal is crossed by three bridges.

The Kinnickinnic River flows north through the southern portion of the City of Milwaukee connecting with the Milwaukee River near Lake Michigan. Only the lower 2.30 miles of the river have been improved for vessel use. Five bridges cross the river with the Lincoln Avenue Bridge at the head of navigation. Freighters up to 1,000 feet in length transfer cargoes at the confluence of the Kinnickinnic and Milwaukee Rivers. Most of the recreational vessels in Milwaukee moor in the lake front marinas and only transit the rivers. Boat yards on the Menomonee and Kinnickinnic rivers haul out and store most of the recreational vessels in the fall and winter months and launch the vessels in the spring. This action contributes to a considerable surge in drawbridge openings in the fall and spring.

The following bridges will be included in the rule: The Union Pacific Railroad Bridge, mile 0.59, over the Milwaukee River with a vertical clearance in the closed position of 7 feet above internet Great Lakes Datum of 1985 (IGLD85). The Broadway Street Bridge, mile 0.79, over the Milwaukee River with a vertical clearance in the closed position of 14 feet above IGLD85. The Water Street Bridge, mile 0.94, over the Milwaukee River with a vertical clearance in the closed position of 14 feet above IGLD85. The St. Paul Avenue Bridge, mile 1.21, over the Milwaukee River with a vertical clearance in the closed position of 14 feet above IGLD85. The Clybourn Street Bridge, mile 1.28, over the Milwaukee River with a vertical clearance in the closed position of 14 feet above IGLD85. Michigan Street Bridge, mile 1.37, over the Milwaukee River with a vertical clearance in the closed position of 12 feet above IGLD85. The Wisconsin Avenue Bridge, mile 1.46, over the Milwaukee River with a vertical clearance in the closed position of 12 feet above IGLD85. The Wells Street Bridge, mile 1.61, over the Milwaukee River with a vertical clearance in the

closed position of 12 feet above IGLD85. The Kilbourn Avenue Bridge, mile 1.70, over the Milwaukee River with a vertical clearance in the closed position of 14 feet above IGLD85. The State Street Bridge, mile 1.79, over the Milwaukee River with a vertical clearance in the closed position of 14 feet above IGLD85. The Highland Avenue Pedestrian Bridge, mile 1.97, over the Milwaukee River with a vertical clearance in the closed position of 12 feet above IGLD85. The Juneau Avenue Bridge, mile 2.06, over the Milwaukee River with a vertical clearance in the closed position of 14 feet above IGLD85. The Knapp Street/Park Freeway Bridge, mile 2.14, over the Milwaukee River with a vertical clearance in the closed position of 16 feet above IGLD85. The Cherry Street Bridge, mile 2.29, over the Milwaukee River with a vertical clearance in the closed position of 14 feet above IGLD85. The Pleasant Street Bridge, mile 2.58, over the Milwaukee River with a vertical clearance in the closed position of 14 feet above IGLD85. The Canadian Pacific Railroad Bridge, mile 1.05, over the Menomonee River with a vertical clearance in the closed position of 8 feet above IGLD85. The North Plankinton Avenue Bridge, mile 1.08, over the Menomonee River with a vertical clearance in the closed position of 14 feet above IGLD85. The North Sixth Street Bridge, mile 1.37, over the Menomonee River with a vertical clearance in the closed position of 23 feet above IGLD85. The Ember Lane Bridge, mile 1.95, over the Menomonee River with a vertical clearance in the closed position of 12 feet above IGLD85. The Sixteenth Street Bridge, mile 2.14, over the Menomonee River with a vertical clearance in the closed position of 35 feet above IGLD85. The South Sixth Street Bridge, mile 1.51, over the South Menomonee Canal with a vertical clearance in the closed position of 8 feet above IGLD85. The Union Pacific Railroad Bridge, mile 1.19, over the Kinnickinnic River with a vertical clearance in the closed position of 8 feet above IGLD85. The Kinnickinnic Avenue Bridge, mile 1.67, over the Kinnickinnic River with a vertical clearance in the closed position of 8 feet above IGLD85. The Canadian Pacific Railroad Bridge, mile 1.67, over the Kinnickinnic River with a vertical clearance in the closed position of 15 feet above IGLD85. Finally, the South First Street Bridge, mile 1.78, over the Kinnickinnic River with a vertical clearance in the closed position of 14 feet above IGLD85. These bridges currently operate under title 33 of the

Code of Federal Regulations (33 CFR), § 117.1093.

IV. Discussion of Comments, Changes and the Final Rule

There is a typographical error in the NPRM describing the operation of the Sixth Street Bridge as remaining closed by regulation and that should have read as the Sixteenth Street Bridge. A typographical error referring to the Canadian Pacific Railroad Bridge as the Canadian National Railroad Bridge have been corrected in this copy. All other comments have been addressed previously.

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. 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).

This regulatory action determination is based on the ability that vessels can still transit the bridge given advanced notice.

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 did not receive any comments from the Small Business Administration on this rule. The PVA claimed that this rule would have a significant impact on one or more of its members. We assisted the PVA and its members to submit documentation to the Local Milwaukee office of the Small Business Administration and made ourselves available for any questions they may have. They did not have any concerns and they did not have any questions for us. 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** 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 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.

We did not receive any comments from local Indian tribes during any comment periods for this rule.

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. We did not receive any comments.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The Coast Guard has 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 promulgates the operating regulations or procedures for drawbridges and is categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are 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; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.1093 to read as follows:

§ 117.1093 Milwaukee, Menomonee, and Kinnickinnic Rivers and South Menomonee and Burnham Canals.

(a) The draws of the bridges over the Milwaukee River shall operate as follows:

(1) The draws of the North Broadway Street bridge, mile 0.5, and North Water Street bridge, mile 0.6, and Michigan Street bridge, mile 1.1, shall open on signal; except that, from April 16th through November 1st, from 7:30 a.m. to 8:30 a.m. and from 4 p.m. to 5:30 p.m. Monday through Friday, except Federal holidays, the draws need not be opened, and from midnight to 7 a.m. Monday through Saturday except Federal holidays the bridges will open on signal if a 2-hour advance notice is provided.

(2) The draws of all other bridges across the Milwaukee River shall open on signal if at least 2-hours' notice is given except that, from April 16th through November 1st, from 7:30 a.m. to 8:30 a.m. and from 4 p.m. to 5:30 p.m. Monday through Friday, except Federal holidays, the draws need not be opened.

(3) The following bridges are remotely operated, are required to operate a radiotelephone, and shall open as noted in this section: St. Paul Avenue, mile 1.21, Clybourn Street, mile 1.28, Wells Street, mile 1.61, Kilbourn Street, mile 1.70, State Street, mile 1.79, Highland Avenue, mile 1.97, and Knapp Street, mile 2.14.

(4) No vessel documented 12 tons or greater shall be held between any bridge at any time and must be passed as soon as possible.

(5) From November 2nd through April 15th, all drawbridges over the Milwaukee River will open on signal if a 12-hour advance notice is provided.

(b) The draws of bridges across the Menomonee River and South Menomonee Canal operate as follows:

(1) The draw of the North Plankinton Avenue bridge across the Menomonee River, mile 1.08, and the Canadian Pacific Railroad bridge, mile 1.05, shall open on signal; except that, from April 16th through November 1st, from 7:30 a.m. to 8:30 a.m. and from 4 p.m. to 5:30 p.m. Monday through Friday, except Federal holidays, the draws need not be opened, and from midnight to 7 a.m. Monday through Friday except Federal

holidays the bridges will open on signal if a 2-hour advance notice is provided.

(2) The draws of all other bridges across the Menomonee River and South Menomonee Canal shall open on signal if at least 2-hours' notice is given except that, from April 16th through November 1st, from 7:30 a.m. to 8:30 a.m. and from 4 p.m. to 5:30 p.m. Monday through Friday, except Federal holidays, the draws need not be opened.

(3) The following bridges are remotely operated, are required to operate a radiotelephone, and shall open as noted in this section: North Plankinton Avenue, mile 1.08, North Sixth Street, mile 1.37, and North Embury Lane, mile 1.95, all over the Menomonee River and South Sixth Street, mile 1.51, over the South Menomonee Canal.

(4) No vessel documented over 12 tons shall be held between any bridge at any time and must be passed as soon as possible.

(5) From November 2nd through April 15th, all drawbridges over the Menomonee River and South Menomonee Canal will open on signal if a 12-hour advance notice is provided.

(c) The draws of bridges across the Kinnickinnic River operate as follows:

(1) The draw of the Kinnickinnic Avenue bridge, mile 1.5, shall open on signal; except that, from April 16th through November 1st, from 7:30 a.m. to 8:30 a.m. and from 4 p.m. to 5:30 p.m. Monday through Friday, except Federal holidays, the draws need not be opened, and from midnight to 7 a.m. Monday through Friday, except Federal holidays, the bridges will open on signal if a 2-hour advance notice is provided.

(2) The draws of all other bridges across the Kinnickinnic River shall open on signal if at least 2-hours' notice is given except that, from April 16th through November 1st, from 7:30 a.m. to 8:30 a.m. and from 4 p.m. to 5:30 p.m. Monday through Friday, except Federal holidays, the draws need not be opened.

(3) The following bridges are remotely operated, are required to operate a radiotelephone, and shall open as noted in this section: The South First Street Bridge, mile 1.78.

(4) No vessel documented over 12 tons shall be held between any bridge at any time and must be passed as soon as possible.

(5) From November 2nd through April 15th, all drawbridges over the Kinnickinnic River will open on signal if a 12-hour advance notice is provided.

(d) The Canadian Pacific Railroad Bridge at Mile 1.74 over the Burnham Canal, and the Sixteenth Street Bridge, mile 2.14, over the Menomonee River

are closed by regulation and do not need to open for the passage of vessels.

M.J. Johnston,

*Rear Admiral, U.S. Coast Guard, Commander,
Ninth Coast Guard District.*

[FR Doc. 2021-20841 Filed 9-24-21; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2020-0033]

RIN 1625-AA09

Drawbridge Operation Regulation; Rainy River, Rainy Lake and Their Tributaries, Rainier, MN

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Final rule.

SUMMARY: The Coast Guard is altering the regulation for the Canadian National Railroad Bridge, mile 85.0, across the Rainy River to allow it to operate remotely. The request was made by the bridge owner. The bridge will continue to open on signal.

DATES: This rule is effective October 27, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>. Type USCG-2020-0033 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 Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216-902-6085, email Lee.D.Soule@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
(Advance, Supplemental)
OMB Office of Management and Budget
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On October 16, 2020, we published a notice of temporary deviation in the **Federal Register** (85 FR 19658) from regulations; request for comments. This deviation was effective from midnight

on May 1, 2020, to midnight on October 15, 2020. Due to COVID-19 Staffing, an issue publishing was delayed; but we utilized local stakeholder and Local Notice to Mariner outreach to solicit comments. We did not receive any comments. On July 6, 2021, we published in the **Federal Register** (86 FR 23880) a notice of proposed rulemaking and we received no comments during the 60-day comment period.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499. Rainy River and Rainy Lake serve as the border between the United States of America and Canada. This bridge is a single leaf, bascule type railroad bridge that provides a horizontal clearance of 125 feet. The water level on Rainy Lake and under the bridge is controlled by a hydro-electric dam facility at International Falls, Minnesota, thus charted datum is based on the water level surface of Rainy Lake when the gauge at Fort Frances, Canada, reads 1107.0 feet resulting in a variable vertical clearance of 6 to 10 feet in the closed position. The railroad bridge carries significant train traffic across the international border. Rainer, Minnesota, is a customs port-of-entry.

IV. Discussion of Comments, Changes and the Final Rule

As discussed in section II we published two documents in the **Federal Register** soliciting comments from the public and did not receive any comments.

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. 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).

This regulatory action determination is based on the ability that vessels can still transit the bridge given advanced notice or on signal depending on the season.

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 did not receive any 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** 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 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, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The Coast Guard has 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 promulgates the operating regulations or procedures for drawbridges and is categorically excluded from further review, under paragraph L49, of Chapter 3, Table3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are 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; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.664 to read as follows:

§ 117.664 Rainy River, Rainy Lake and their tributaries.

The draw of the Canadian National Railroad Bridge, mile 85.0, at Rainer, MN may operate remotely, and shall open on signal; except that, from October 16 to April 30, the draw shall open on signal if at least 12-hours advance notice is provided. The commercial phone number to provide advance notice shall be posted on the bridge so that it is plainly visible to vessel operators approaching the up or downstream side of the bridge. The owners of the bridge shall provide and keep in good legible condition two board gauges painted white with black figures to indicate the vertical clearance under the closed draw at all water levels. The gauges shall be so placed on the bridge that they are plainly visible to operators of vessels approaching the bridge either up or downstream. The bridge shall operate and maintain a VHF–FM Marine Radio.

M.J. Johnston,

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

[FR Doc. 2021–20839 Filed 9–24–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0747]

RIN 1625–AA00

Safety Zone; Tugs Champion, Valerie B, Nancy Anne and Barges Kokosing I, Kokosing III, Kokosing IV Operating in the Straits of Mackinac, MI

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the navigable water within a 500-yard radius of several tugs and barges in the Straits of Mackinac. The safety zone is needed to protect personnel, vessels, and the marine environment from the potential hazards created by the work, inspection, surveying and the removal and replacement of cables for the Straits of Mackinac. Entry of vessels or persons into the zone is prohibited unless specifically authorized by the Captain of the Port Sault Sainte Marie or their designated representative.

DATES: This rule is effective from October 1, 2021, through November 30, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2021–0747 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Deaven S. Palenzuela, Sector Sault Sainte Marie Waterways Management Division, U.S. Coast Guard at (906) 635–3223 or email ssmprevention@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 doing so would be impracticable. This temporary final rule is an extension in order for the company to complete their project scope taking into account any delays due to heavy weather or vessel issues that are out of their control.

Delaying this rule to allow for a notice and full comment period would be impracticable because it would inhibit the Coast Guard’s ability to protect the public from the potential hazards associated with the continuation of the aforementioned operation on October 1, 2021, with a new prospective completion date of November 30, 2021.

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**. For the same reasons discussed in the preceding paragraph, delaying the continuation effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with the work, inspections, and surveying of underwater infrastructure.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sault Sainte Marie (COTP) has determined that potential hazards associated with the work, inspection, and surveying of underwater infrastructure in the Straits of Mackinac starting April 20, 2021, will be a safety concern for anyone within a 500-yard radius of the tugs and barges. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the operation is conducted.

IV. Discussion of the Rule

This rule establishes a continuation safety zone from October 1, 2021, to November 30, 2021. The safety zone will cover all navigable waters within 500 yards of the tugs and barges being used to work, inspect, survey and remove/replace cables in the Straits of Mackinac. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the operation is conducted. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. 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).

This regulatory action determination is based on the size and location of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area of the Straits of Mackinac. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (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 call or email 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.

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 Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human

environment. This rule involves a safety zone that will prohibit entry within 500 yards of tugs and barges used to work, inspect, survey and remove/replace cables in the Straits of Mackinac. It is categorically excluded from further review under paragraph L[60(a)] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email 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: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T09–0747 to read as follows:

§ 165.T09–0747 Safety Zone; Tugs Champion, Valerie B, Nancy Anne and Barges Kokosing I, Kokosing III, Kokosing IV operating in the Straits of Mackinac, MI.

(a) *Location.* The following areas are safety zones: All navigable water within 500 yards of the Tugs Valerie B, Nancy Anne, Champion and Barges Kokosing I, III, and IV while conducting work, inspection, surveying and removing/replacing cables in the Straits of Mackinac.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sault Sainte Marie (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within the safety zone described in paragraph (a) of this section is prohibited unless authorized by the Captain of the Port, Sault Sainte Marie or his designated representative.

(2) Before a vessel operator may enter or operate within the safety zones, they must obtain permission from the Captain of the Port, Sault Sainte Marie, or his designated representative via VHF Channel 16 or telephone at (906) 635–3233. Vessel operators given permission to enter or operate in the safety zone must comply with all orders given to them by the Captain of the Port, Sault Sainte Marie or his designated representative.

(d) *Enforcement period.* This section will be enforced from October 1, 2021, to November 30, 2021.

Dated: September 21, 2021.

A.R. Jones,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2021–20882 Filed 9–24–21; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Parts 111, 113 and 211

Treatment of Regulations on Hazardous, Restricted, and Perishable Mail

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service amends certain regulations to clarify the regulatory treatment of Publication 52, *Hazardous, Restricted, and Perishable Mail*.

DATES: This rule is effective September 27, 2021.

FOR FURTHER INFORMATION CONTACT: Dale E. Kennedy, Director, Product Classification, at 202–268–6592.

SUPPLEMENTARY INFORMATION: The Postal Service has long maintained regulations on hazardous, restricted, and perishable mail. For many years, those regulations were located in Mailing Standards of the United States Postal Service, *Domestic Mail Manual* (“DMM”). The DMM is a regulation of the Postal Service. 39 CFR 211.2(a)(2). Annual editions of the DMM are incorporated by reference into 39 CFR 111.1. As explained in Postal Service regulations, interim regulations are published in the DMM pending the next volume’s incorporation into the Code of Federal Regulations, and changes to the DMM are announced in

the **Federal Register**. 39 CFR 111.3. As an additional reference, the Postal Service developed Publication 52, *Hazardous, Restricted, and Perishable Mail*.

On July 28, 2014, as part of a continuing initiative to reduce the size of the DMM, the Postal Service removed from that publication the detailed mailing standards relating to hazardous, restricted, and perishable materials. In place of these detailed provisions, revised DMM 601.8.0 advised that mailing standards specific to hazardous, restricted, and perishable mail would be incorporated into Publication 52, and could be found on the Postal Explorer website at *pe.usps.com*. The Postal Service subsequently promulgated new regulations incorporating an edition of Publication 52 by reference into 39 CFR 113.2. See 83 FR 1189 (2018).

The Postal Service, in consultation with the Office of the Federal Register, has determined that clarification of the status of Publication 52 would be helpful, particularly in order to ensure that changes to Publication 52 are comprehensively noticed in the **Federal Register**. To that end, the Postal Service hereby makes certain changes to its rules.

First, DMM section 601.8.1 is amended to clarify that the substantive mailability rules in Publication 52, as in effect and available on the Postal Service's website at any given time, are incorporated by reference into that DMM section.

Second, 39 CFR 211.2(a) will be amended to clarify that Publication 52 contains regulations of the Postal Service. In connection with this change, language in 39 CFR 211.2(a) regarding publication in the **Federal Register** and Code of Federal Regulations will be moved to more clearly express the intent that any regulations of the Postal Service may, where appropriate, be published in those outlets. Moreover, 39 CFR 211.2(a)(3) is expanded somewhat to clarify that Publications and Memoranda of Policy may also qualify as regulations, and that status as regulations depends not on the formal designation of a document, but on its statement of binding rules of future effect beyond those stated elsewhere in Postal Service regulations.

Third, 39 CFR part 113, which includes the incorporation by reference of Publication 52 (39 CFR 113.2), is removed. The temporary rules in 39 CFR 113.3 regarding COVID-19 related Category B infectious substances are duplicative of rules in Publication 52, and so it is unnecessary to maintain such rules in the Code of Federal Regulations. Compare 85 FR 23745 with

Postal Bulletin 22544 (Apr. 23, 2020), at 6–7 (amending Publication 52 appendix C, USPS Packaging Instruction 6C).

List of Subjects

39 CFR Part 111

Administrative practice and procedure, Postal Service.

39 CFR Part 113

Administrative practice and procedure, Hazardous substances, Postal service.

39 CFR Part 211

Administrative practice and procedure, Postal Service.

Accordingly, for the reasons stated, the Postal Service amends 39 CFR parts 111, 113, and 211 as follows:

PART 111—[AMENDED]

- 1. The authority citation for 39 CFR part 111 is revised to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401–404, 414, 416, 3001–3018, 3201–3220, 3401–3406, 3621, 3622, 3626, 3629, 3631–3633, 3641, 3681–3685, and 5001.

- 2. Revise the Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM) as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

600 Basic Standards for All Mailing Services

601 Mailability

* * * * *

8.0 Hazardous, Restricted, and Perishable Mail

8.1 General

Effective July 7, 2014, all content applicable to hazardous, restricted, or perishable mail was removed and incorporated into Publication 52, *Hazardous, Restricted, and Perishable Mail*. The contents of Publication 52, as in effect and available on the Postal Service website at the relevant time, are incorporated by reference into this section.

* * * * *

PART 113—[REMOVED]

- 3. Under the authority of 39 U.S.C. 401(2), remove part 113.

PART 211—APPLICATION OF REGULATIONS

- 4. The authority citation for part 211 is revised to read as follows:

Authority: 39 U.S.C. 201, 202, 205, 401–404, 406, 407, 410, 411, 413, 414, 416, 1001–1011, 1201–1209, 2008–2010, 2201, 2601–2605, 2901–2902, 3001–3018, 3201–3220, 3401–3406, 3621–3629, 3631–3633, 3641, 3654, 3681–3685, 3691, 5001–5007, 5401–5403, 5601–5605; 39 U.S.C. note.

- 5. Amend § 211.2 by revising the introductory text to paragraph (a) and paragraphs (a)(2) and (3) to read as follows:

§ 211.2 Regulations of the Postal Service.

(a) The regulations of the Postal Service consist of the following, any of which may, but are not required to, be published in the **Federal Register** and the Code of Federal Regulations:

* * * * *

(2) The *Mailing Standards of the United States Postal Service, Domestic Mail Manual*; the *Postal Operations Manual*; the *Administrative Support Manual*; the *Employee and Labor Relations Manual*; the *Financial Management Manual*; the *International Mail Manual*; those portions of Chapter 2 of the former *Postal Service Manual* and chapter 7 of the former *Postal Manual* retained in force; and Publication 52, *Hazardous, Restricted, and Perishable Mail*; and

(3) Headquarters Circulars, Management Instructions, Regional Instructions, Handbooks, Memoranda of Policy, Publications, delegations of authority, and other regulatory issuances and directives of the Postal Service or the former Post Office Department, to the extent that such documents state binding rules of future effect beyond those stated in other regulations of the Postal Service then in effect.

* * * * *

Joshua J. Hofer,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2021–20425 Filed 9–24–21; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

39 CFR Part 233

Mail Screening Regulations

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: On August 20, 2021, The Postal Service amended its regulations regarding the screening of mail to be consistent with aviation regulations regarding the transportation of mail via aircraft; continue to enhance the security and ensure the safety of all persons and property onboard aircraft carrying mail; and prevent and deter the

carriage of unauthorized explosives, incendiaries, or other destructive substances or items in the mail or in postal products transported onboard aircraft. This final rule is being published for the sole purpose of correcting a citational error, and no substantive changes have been made to the regulation as published on August 20, 2021.

DATES: This rule is effective October 27, 2021.

FOR FURTHER INFORMATION CONTACT: Amber Jordan, Inspector Attorney, arjordan@uspis.gov, (202) 268-7812.

SUPPLEMENTARY INFORMATION: On May 24, 2021 (86 FR 27823), the Postal Service published a proposed rule to update Postal Service regulations regarding the screening of mail. The circumstances which created the need for the update were as follows: (1) 39 CFR 233.11 was published as a final rule on February 28, 1996; (2) since the publication of 39 CFR 233.11, no updates had been made; (3) after February 28, 1996, changes were made to 49 U.S.C. 44901 requiring the screening of all items, including United States mail, transported via aircraft; and (4) an update is required to ensure it is consistent with title 49 of the Code of Federal Regulations as it pertains to mail being transported via aircraft.

The regulations published on August 20, 2021 (86 FR 38413), modified the Postal Service regulations regarding the screening of mail to make said regulations: (1) More consistent with aviation regulations regarding the transportation of mail via aircraft; (2) continue to enhance the security and ensure the safety of all persons and property onboard aircraft carrying mail; and (3) continue to prevent and deter the carriage of unauthorized explosives, incendiaries, or other destructive substances or items in the mail or in postal products transported onboard aircraft. This final rule amends the regulations as published on August 20, 2021, in order to correct a citational error.

List of Subjects in 39 CFR Part 233

Law enforcement, Postal Service.

For the reasons stated in the preamble, the Postal Service amends 39 CFR part 233 as follows:

PART 233—INSPECTION SERVICE AUTHORITY

■ 1. The authority citation for 39 CFR part 233 continues to read as follows:

Authority: 39 U.S.C. 101, 102, 202, 204, 401, 402, 403, 404, 406, 410, 411, 1003, 3005(e)(1), 3012, 3017, 3018; 12 U.S.C. 3401–

3422; 18 U.S.C. 981, 983, 1956, 1957, 2254, 3061; 21 U.S.C. 881; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 104–208, 110 Stat. 3009; Secs. 106 and 108, Pub. L. 106–168, 113 Stat. 1806 (39 U.S.C. 3012, 3017); Pub. L. 114–74, 129 Stat. 584.

■ 2. Revise § 233.11 to read as follows:

§ 233.11 Mail screening.

(a) *Screening of mail transported by aircraft*—(1) *Authority.* Pursuant to 39 U.S.C. 5401, the Postal Service is authorized to provide for the safe and expeditious transportation of mail by aircraft and may make such rules, regulations, and orders consistent with part A of subtitle VII of title 49 [49 U.S.C. 40101 *et seq.*], or any order, rule, or regulation made by the Secretary of Transportation thereunder, as may be necessary for such transportation, except as otherwise provided in 39 U.S.C. 5402.

(2) *Purpose.* To prevent and deter the carriage of unauthorized explosives, incendiaries, or other destructive substances or items in the mail or in postal products onboard aircraft and to ensure the security and safety of all persons and property onboard aircraft carrying mail.

(3) *Policy.* Mail of sufficient weight to pose a hazard to aviation may, without a search warrant or the sender's or addressee's consent, be screened by any means capable of identifying explosives, nonmailable firearms, or other dangerous contents in the mails that are destructive or could endanger life or property.

(b) *Screening of surface transported mail*—(1) *Authority.* Pursuant to 39 U.S.C. 404, the Postal Service has specific power to provide for, among other things, the handling of mail. Mail may be screened without a search warrant or the sender's or addressee's consent in exigent circumstances to identify explosives or other dangerous contents in the mails.

(2) *Purpose.* To prevent and deter the carriage of unauthorized explosives or other dangerous content in the mail or in postal products transported via surface transportation providers and to ensure the security and safety of all persons and property associated with mail usage, processing, handling, and transportation.

(3) *Policy.* When the Chief Postal Inspector or designee determines there is a credible threat that certain mail may contain a bomb, explosives, or other material that could endanger life or property, including nonmailable firearms, the Chief Postal Inspector or designee may, without a search warrant or the sender's or addressee's consent, authorize the screening of such mail by

any means capable of identifying explosives, nonmailable firearms, or other dangerous contents in the mails.

(c) *Mail screening restrictions.*

Screening of mail authorized by paragraphs (a) and (b) of this section is subject to the following restrictions:

(1) *No unreasonable delay.* The mail must be screened in a manner which does not unreasonably delay its delivery.

(2) *Authorization to screen mail.* The mail screening may be conducted by Postal Service employees or persons not employed by the Postal Service, as authorized by the Chief Postal Inspector, under such instruction that requires compliance with this part and protects the security of the mail. No information obtained from this mail screening may be disclosed unless authorized by this part.

(3) *Mail of insufficient weight to pose a threat.* Mail of insufficient weight to pose a hazard to air transportation, surface transportation, or to contain firearms must be excluded from such screening.

(4) *Additional limitations.* The screening must be within the limits of this section and conducted without opening mail that is sealed against inspection or revealing the contents of correspondence within mail that is sealed against inspection.

(d) *Identified threatening pieces of mail*—(1) *Hazardous mail.* Mail, sealed or unsealed, reasonably suspected of posing an immediate danger to life or limb or an immediate substantial danger to property as a result of screening or other information may, without a search warrant, be detained, opened, removed from postal custody, processed, and treated, but only to the extent necessary to determine and eliminate the danger. Such mail must be processed in accordance with the instructions promptly furnished by the Inspection Service.

(2) *Indeterminate mail.* After screening, mail sealed against inspection that presents doubts about whether its contents are hazardous, that cannot be resolved without opening, must be reported to the Postal Inspection Service. Such mail must be processed in accordance with the instructions promptly furnished by the Inspection Service.

(3) *Mandatory reporting.* Any person who opens mail sealed against inspection, in accordance with paragraph (d)(1) or (2) of this section, is required to provide a complete written and sworn statement regarding the detention, screening, opening, and treatment of the mail piece, as well as the circumstances surrounding its

identification as a possible threat. The statement is required to be signed by the person purporting to act under this section and promptly forwarded to the Chief Postal Inspector. Any person purporting to act under this section who does not report his or her action to the Chief Postal Inspector under the requirements of this section, or whose action is determined after investigation not to have been authorized, is subject to disciplinary action or criminal prosecution or both.

Ruth Stevenson,

Chief Counsel, Ethics & Legal Compliance.

[FR Doc. 2021-20574 Filed 9-24-21; 8:45 am]

BILLING CODE 7710-12-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2020-0254; FRL-8727-02-R9]

Clean Air Plans; 2008 8-Hour Ozone Nonattainment Area Requirements; West Mojave Desert, California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve portions of state implementation plan (SIP) revisions submitted by the State of California to meet Clean Air Act (CAA or “Act”) requirements for the 2008 8-hour ozone national ambient air quality standards (NAAQS or “standards”) in the Los Angeles-San Bernardino Counties (West Mojave Desert), California ozone nonattainment area (“West Mojave Desert” or WMD). The SIP revisions address the “Severe-15” nonattainment area requirements for the 2008 ozone NAAQS, including the requirements for emissions inventories, attainment demonstration, reasonable further progress, reasonably available control measures, and contingency measures, among others; and establishes motor vehicle emissions budgets. The EPA is approving the SIP revisions as meeting all the applicable ozone nonattainment area requirements, except for the contingency measures requirement, for which the EPA is deferring action.

DATES: This rule is effective on October 27, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-R09-OAR-2020-0254. All documents in the docket are listed on the <https://www.regulations.gov>

website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Tom Kelly, Air Planning Office (AIR-2), EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 972-3856, or by email at kelly.thomasp@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us,” and “our” refer to the EPA.

I. Summary of the Proposed Action

On May 10, 2021, the EPA proposed to approve, under CAA section 110(k)(3), and to conditionally approve, under CAA section 110(k)(4), two SIP submittals from the California Air Resources Board (CARB) addressing planning obligations for the West Mojave Desert¹ as a Severe-15 nonattainment area for the 2008 ozone NAAQS.² The first, submitted June 2, 2017, includes attainment plans prepared by the Antelope Valley Air Quality Management District (AVAQMD) and the Mojave Desert Air Quality Management District (MDAQMD) (collectively, “Districts”), an accompanying staff report prepared by CARB (“CARB Staff Report”), and other supporting documents.³ We refer

¹ 86 FR 24809 (May 10, 2021). The West Mojave Desert consists of the northeast portion of Los Angeles County and the southwest portion of San Bernardino County. For a precise definition of the boundaries of the West Mojave Desert 2008 ozone nonattainment area, see 40 CFR 81.305.

² In accordance with CAA section 181(a)(1), 40 CFR 51.1102 and 51.1103(a), nonattainment areas classified as Severe-15 must attain the NAAQS within 15 years of the effective date of the nonattainment designation.

³ “AVAQMD Federal 75 ppb Ozone Attainment Plan (Western Mojave Desert Nonattainment Area),” adopted on March 21, 2017, “MDAQMD Federal 75 ppb Ozone Attainment Plan (Western Mojave Desert Nonattainment Area),” adopted on February 27, 2017, and “CARB Review of the Mojave Desert AQMD and Antelope Valley AQMD Federal 75 ppb Ozone Attainment Plans for the Western Mojave Desert Nonattainment Area,” released April 21, 2017.

to all the documents submitted to the EPA on June 2, 2017, as the “2016 WMD Attainment Plan.”

The second submittal, sent on December 11, 2018, is the “2018 Updates to the California State Implementation Plan” (“2018 SIP Update”).⁴ CARB adopted the 2018 SIP Update on October 25, 2018. CARB developed the 2018 SIP Update in response to the court’s decision in *South Coast II*⁵ vacating the 2008 Ozone SIP Requirements Rule (“2008 Ozone SRR”) with respect to the use of an alternate baseline year for demonstrating reasonable further progress (RFP), and to address contingency measure requirements in the wake of the decision by the Ninth Circuit Court of Appeals in *Bahr v. EPA* (“*Bahr*”).⁷ The 2018 SIP Update includes updates for eight different California ozone nonattainment areas. We have previously approved portions of the 2018 SIP Update related to other nonattainment areas.⁸ For the West Mojave Desert, the 2018 SIP Update includes an RFP demonstration using the required 2011 baseline year and revised motor vehicle emission budgets for the 2008 ozone NAAQS.⁹

In our proposed rule, we provided background information on the ozone standards,¹⁰ area designations, and

⁴ Letter dated December 5, 2018, from Richard Corey, Executive Officer, CARB, to Mike Stoker, Regional Administrator, EPA Region IX, and electronically transmitted to the EPA’s State Planning Electronic Collaboration System on December 11, 2018.

⁵ *South Coast Air Quality Management District v. EPA*, 882 F.3d 1138 (D.C. Cir. 2018). The term “*South Coast II*” is used in reference to the 2018 court decision to distinguish it from a decision published in 2006 also referred to as “*South Coast*.” The earlier decision involved a challenge to the EPA’s Phase 1 implementation rule for the 1997 ozone NAAQS. *South Coast Air Quality Management Dist. v. EPA*, 472 F.3d 882 (D.C. Cir. 2006).

⁶ 2008 Ozone SRR, 80 FR 12264, 12283 (March 6, 2015).

⁷ *Bahr v. EPA*, 836 F.3d 1218 (9th Cir. 2016). In this case, the court rejected the EPA’s longstanding interpretation of CAA section 172(c)(9) as allowing for early implementation of contingency measures. The court concluded that a contingency measure must take effect at the time the area fails to make RFP or attain by the applicable attainment date, not before. See also *Sierra Club v. EPA*, 985 F.3d 1055 (D.C. Cir. 2021), reaching a similar decision. These cases are addressed below in Section III.G of this document.

⁸ See, e.g., 84 FR 11198 (March 25, 2019) (final approval of the San Joaquin Valley portion of the 2018 SIP Update) and 84 FR 52005 (October 1, 2019) (final approval of the South Coast portion of the 2018 SIP Update).

⁹ CARB withdrew the 2016 WMD Attainment Plan RFP demonstration in a letter dated December 18, 2019, from Richard Corey, Executive Officer, CARB, to Michael Stoker, Regional Administrator, EPA Region IX.

¹⁰ The 1-hour ozone NAAQS is 0.12 parts per million (ppm) (one-hour average), the 1997 ozone

Continued

related SIP revision requirements under the CAA and the EPA's implementing regulations for the 2008 ozone standards, referred to as the 2008 Ozone SRR. To summarize, the West Mojave Desert is classified as Severe-15 for the 2008 ozone NAAQS, and CARB's submittals were developed to address the statutory and regulatory requirements for revisions to the SIP for the West Mojave Desert Severe-15 ozone nonattainment area.

Under the 2008 Ozone SRR, areas classified as Severe-15 for the 2008 ozone NAAQS must demonstrate attainment within 15 years of the effective date of the nonattainment designation, July 20, 2027, and states must implement all control measures needed for attainment no later than the beginning of the attainment year ozone season.¹¹ The attainment year ozone season is defined as the ozone season immediately preceding a nonattainment area's outermost attainment date, or 2026.

Our proposed conditional approval of the contingency measures element of the 2016 WMD Attainment Plan relied on specific commitments: (1) The MDAQMD would submit a board resolution further detailing the circumstances, timing, and procedure for implementing this contingency measure, within 11 months of the EPA's final conditional approval of the contingency measures element of the 2016 WMD Attainment Plan,¹² and (2) CARB would submit the adopted board resolution to the EPA as a SIP revision within 12 months of the EPA's final action.¹³ For more information on these SIP submittals and related commitments, please see our proposed rule.

In our proposed rule, we reviewed the various SIP elements contained in CARB's submittals, evaluated them for compliance with statutory and regulatory requirements, and concluded that they meet all applicable requirements, except for the contingency measure requirement, for which the EPA proposed conditional

approval. More specifically, in our proposed rule, we based our proposed actions on the following determinations:

- CARB and the Districts met all applicable procedural requirements for public notice and hearing prior to the adoption and submittal of the 2016 WMD Attainment Plan and the 2018 SIP Update;¹⁴
- The 2012 base year emissions inventory from the 2016 WMD Attainment Plan is comprehensive, accurate, and current, and therefore meets the requirements of CAA sections 172(c)(3) and 182(a)(1) and 40 CFR 51.1115. Additionally, the future year baseline projections reflect appropriate calculation methods and the latest planning assumptions and are properly supported by the SIP-approved stationary and mobile source measures;¹⁵
- The emissions statement element of the 2016 WMD Attainment Plan meets the requirements for emissions statements under CAA section 182(a)(3)(B) and 40 CFR 51.1102 for the 2008 ozone NAAQS;¹⁶
- The process followed by the Districts to identify reasonably available control measures (RACM) is generally consistent with the EPA's recommendations; the Districts' rules provide for the implementation of RACM for stationary and area sources of oxides of nitrogen (NO_x) and volatile organic compounds (VOC);¹⁷ CARB and the Districts provide for the implementation of RACM for mobile sources of NO_x and VOC; there are no additional RACM that would advance attainment of the 2008 ozone NAAQS in the West Mojave Desert by at least one year; and therefore, the 2016 WMD Attainment Plan provides for the implementation of all RACM as required by CAA section 172(c)(1) and 40 CFR 51.1112(c);¹⁸
- The photochemical modeling in the 2016 WMD Attainment Plan shows that existing CARB and District control measures are sufficient to attain the 2008 ozone NAAQS by the applicable attainment date, July 20 2027; given the documentation in the 2016 WMD Attainment Plan of modeling procedures and good model performance, the modeling is adequate

to support the attainment demonstration; and therefore the 2016 WMD Attainment Plan meets the attainment demonstration requirements of CAA section 182(c)(2)(A) and 40 CFR 51.1108;¹⁹

- The RFP demonstration in the 2018 SIP Update provides for emissions reductions of VOC or NO_x of at least 3 percent per year on average for each three-year period, beginning 6 years after the baseline year until the attainment date, and thereby meets the requirements of CAA sections 172(c)(2) and 182(c)(2)(B) and 40 CFR 51.1110(a)(2)(ii);²⁰

- The vehicle miles traveled (VMT) emissions offset demonstration shows that CARB and the Southern California Association of Governments have adopted sufficient transportation control strategies and transportation control measures to offset the growth in emissions from growth in VMT and vehicle trips in the West Mojave Desert, and thereby complies with the VMT emissions offset requirement in CAA section 182(d)(1)(A) and 40 CFR 51.1102 for the 2008 ozone NAAQS;²¹

- The motor vehicle emissions budgets in the 2018 SIP Update are consistent with the RFP demonstration, are clearly identified and precisely quantified, and meet all other applicable statutory and regulatory requirements in 40 CFR 93.118(e), including the adequacy criteria in 40 CFR 93.118(e)(4) and (5);²² and

- Through previous EPA approvals of California's vehicle inspection and maintenance (I/M) program, the 1994 "Opt-Out Program" SIP revision, the 1993 Photochemical Assessment Monitoring Station SIP revision, and the 2020 annual monitoring network plan for the West Mojave Desert, the 2016 WMD Attainment Plan adequately addresses, for the 2008 ozone NAAQS, the enhanced I/M requirements in CAA section 182(c)(3) and 40 CFR 51.1102; the clean fuels fleet program in CAA sections 182(c)(4) and 246 and 40 CFR 51.1102; and the enhanced ambient air monitoring requirements in CAA section 182(c)(1) and 40 CFR 51.1102.²³

NAAQS is 0.08 ppm (eight-hour average), and the 2008 ozone NAAQS is 0.075 ppm (eight-hour average).

¹¹ 80 FR 12264 (March 6, 2015).

¹² Letter dated March 29, 2021, from Brad Poiriez, Executive Officer, MDAQMD, to Richard Corey, Executive Officer, CARB.

¹³ Letter dated April 9, 2021, from Michael Benjamin, Chief, Air Quality Planning and Science Division, CARB, to Deborah Jordan, Acting Regional Administrator, EPA Region IX. CARB's letter also forwarded the MDAQMD's commitment letter to the EPA. The MDAQMD's letter is dated March 29, 2021, from Brad Poiriez, Executive Officer, MDAQMD, to Richard Corey, CARB Executive Officer.

¹⁴ 86 FR 24809, 24812.

¹⁵ Id. at 24812–24814 and 24816–24819.

¹⁶ Id. at 24814–24815.

¹⁷ Ground-level ozone pollution is formed from the reaction of VOC and NO_x in the presence of sunlight. CARB refers to reactive organic gases (ROG) in some of its ozone-related submittals. The CAA and the EPA's regulations refer to VOC, rather than ROG, but both terms cover essentially the same set of gases.

¹⁸ 86 FR 24809, 24815–24816.

¹⁹ Id. at 24816–24819.

²⁰ Id. at 24819–24821.

²¹ Id. at 24821–24823.

²² Id. at 24825–24827. In light of CARB's request to limit the duration of the approval of the budgets in the 2018 SIP Update and in anticipation of the EPA's approval, in the near term, of an updated version of CARB's EMFAC (short for Emission FACtor) model for use in SIP development and transportation conformity in California to include updated vehicle mix and emissions data, we proposed to limit the duration of our approval of the budgets until replacement budgets have been found adequate. See id. at 24827.

²³ Id. at 24827–24828.

For the enhanced I/M element, the proposed rule notes that an enhanced I/M program is currently implemented in a portion of the West Mojave Desert.²⁴ As summarized above, the proposed rule identifies this program as a required element for the area under CAA section 182(c)(3). On review, however, we have confirmed that the West Mojave Desert does not meet the population threshold in CAA section 182(c)(3),²⁵ and therefore is not subject to the enhanced I/M requirement for the 2008 ozone NAAQS. The State of California has elected to implement an enhanced I/M vehicle program in portions of the West Mojave Desert as part of the ozone control strategy for the area. We most recently approved California's I/M program in 2010.²⁶

In light of the *Bahr* decision, the MDAQMD²⁷ and CARB²⁸ committed to supplement the contingency measure element through submission, as a SIP revision (within one year of our final conditional approval action), of a board resolution further detailing the circumstances, timing, and procedures for implementing I/M in the portion of the West Mojave Desert not subject to enhanced I/M,²⁹ if an RFP milestone is not met or if the area fails to attain the 2008 ozone NAAQS by the applicable attainment date.³⁰ The EPA proposed to conditionally approve the contingency measure element as meeting the requirements of CAA sections 172(c)(9) and 182(c)(9). Please see our proposed rule for more information concerning the background for this action and for a more detailed discussion of the rationale for approval or conditional approval of the above-listed elements of CARB's submittals.

²⁴ Id. at 24827.

²⁵ 40 CFR 51.350(a)(2) (requiring enhanced I/M in any 1990 Census-defined urbanized area within an ozone nonattainment area classified as Serious or above with a 1980 Census-defined urbanized area with a population of 200,000 or more).

²⁶ 75 FR 38023 (July 1, 2010). See also related notice of proposed rulemaking at 74 FR 41818 (August 19, 2009).

²⁷ Letter dated March 29, 2021, from Brad Poiriez, Executive Officer, MDAQMD, to Richard Corey, CARB Executive Officer.

²⁸ Letter dated April 9, 2021, from Michael Benjamin, Chief, Air Quality Planning and Science Division, CARB, to Deborah Jordan, Acting Regional Administrator, EPA Region IX. CARB's letter also forwarded the MDAQMD's commitment letter to the EPA.

²⁹ As described in the proposed rule, enhanced I/M is implemented in the West Mojave Desert in all of the area under the jurisdiction of the AVAQMD and in a portion of the area under the jurisdiction of the MDAQMD.

³⁰ 86 FR 24809, 24823–24825.

II. Public Comments and EPA Responses

The public comment period on the proposed rule opened on May 10, 2021, the date of its publication in the **Federal Register**, and closed on June 9, 2021. During this period, the EPA received two comment letters, one submitted by an individual and one submitted by the Colorado River Indian Tribes (CRIT or "Tribes"). We address the comments in the following paragraphs of this final rule.

Comment #1: CRIT objected to language in the proposal stating that "the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction," and that the proposed action therefore "does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law" in these areas. CRIT argued that this analysis takes an overly narrow view of tribal interests, noting that the Tribes' ancestral homelands extend far beyond the boundaries of the Tribes' reservation, and that these areas have substantial cultural, spiritual, and religious significance for the Tribes. For this reason, CRIT stated, they have an interest in ensuring that air quality impacts in the West Mojave Desert are adequately considered and mitigated, even where they lack jurisdiction. CRIT observed that the EPA has a responsibility to consult on a government-to-government basis with federally recognized tribal governments when EPA actions and decisions may affect tribal interests, based on Executive Order 13175 and the EPA Region IX draft tribal consultation guidelines,³¹ and stated that this responsibility is not limited to actions on lands where tribes have jurisdiction.³² CRIT requested a 15-day extension to review the proposal and provide comments, because they were not provided notice of the proposal and were not aware of any formal consultation occurring between the EPA and tribes located within the West Mojave Desert.

Response to Comment #1: As indicated in the EPA Region IX tribal consultation document cited by the commenter, for proposed Planning Office actions on SIP submittals that do

³¹ EPA Region IX, "EPA Tribal Consultation Best Practices for Air and Radiation Division Regulatory Actions (Draft)," September 2020 ("Draft Consultation Best Practices").

³² CRIT also cites California state authorities governing state tribal consultation procedures and indicates that it sent its comments to CARB.

not affect the designation or classification of a nonattainment area (e.g., attainment plans), our general practice is to provide notification to tribes located within the applicable nonattainment area, and to consult with tribes if requested.³³ We recognize that EPA actions may also be of interest to tribes with jurisdictional lands located outside of the nonattainment area. For this reason, going forward, we intend to provide notification of these SIP actions to tribes that have expressed interest in EPA rulemaking within the area, in addition to tribes with jurisdictional lands located within the area. Consistent with this approach, we will include CRIT on future notifications for planning actions related to the West Mojave Desert nonattainment area.

On June 17, 2021, the EPA sent a letter inviting CRIT to discuss this proposed action and any concerns the Tribes might have, and to offer CRIT the chance to provide additional input on the action by July 2, 2021, consistent with our practices for tribal consultation and involvement.³⁴ CRIT did not request additional discussions with the EPA or provide any additional input on this proposed action.

Comment #2: CRIT commented that the EPA's analysis does not address whether CARB's control measures for off-road mobile sources will reduce overall use of those sources. CRIT explained that the Tribes have been involved in other regional planning efforts regarding off-road vehicles in the West Mojave Desert, and are concerned about the impact of off-road vehicle use on cultural resources and the potential for removal of artifacts.

Response to Comment #2: Off-road mobile sources include trains, aircraft, off-road equipment (e.g., construction and mining vehicles) and off-road recreational vehicles (e.g., off-road motorcycles and all-terrain vehicles). Within the off-road mobile source category, off-road recreational vehicles constitute a relatively small portion of the overall inventory.³⁵ To the extent

³³ Draft Consultation Best Practices at 6. The EPA issued a final version of this document on August 22, 2021. See EPA Region IX, "EPA Tribal Consultation Best Practices for Air and Radiation Division Regulatory Actions," August 22, 2021.

³⁴ Letter dated June 17, 2021, from Elizabeth J. Adams, Director, Air and Radiation Division, EPA Region IX, to Amelia Flores, Chairperson, Colorado River Indian Tribes.

³⁵ Emissions from off-road recreational vehicles are estimated at 0.034 tons per day (tpd) of NO_x in the 2012 baseline year (0.1 percent of total off-road emissions), and 0.05 tpd in the 2026 attainment year (0.3 percent of total off-road emissions). In contrast, emissions from trains are estimated at more than 28 tpd of NO_x in 2012 (87 percent of total off-road emissions) and 12.5 tpd in 2026 (80

that on-road vehicles travel off-road, these emissions would be captured within the on-road category. Federal and CARB regulations do not generally rely on operational limits to achieve emission reductions. For example, one State measure approved into the California SIP rule restricts off-road vehicles that do not meet current emission standards (e.g., older off-road vehicles) from operating in ozone nonattainment areas during periods when the area may not attain the ozone standards (e.g., summer months) but does not limit the operation of compliant off-road vehicles.³⁶ Another State rule approved into the SIP limits evaporative emission of fuel for off-road vehicles.³⁷ As related to attainment of the 2008 ozone NAAQS, California measures related to off-road vehicles generally ensure that emissions of ozone precursors from this source category are controlled within the nonattainment area, but do not restrict or reduce overall usage of off-road engines meeting current emissions standards. We recognize the concerns expressed by CRIT related to the impacts of off-road vehicle usage on cultural resources and artifacts. The Bureau of Land Management and the National Park Service, within the U.S. Department of the Interior, oversee off-road vehicle use in the eastern portion of the West Mojave Desert and may have additional information regarding use of off-road vehicles in the West Mojave Desert and potential impacts to cultural resources.

Comment #3: Both commenters suggested that the 2016 WMD Attainment Plan should be revised to demonstrate attainment of the 2015 ozone NAAQS (0.070 ppm), rather than the 2008 ozone NAAQS (0.075 ppm), arguing that it would be more efficient to address the more recent standards as part of this SIP revision. The individual commenter stated that the EPA's failure to require this revision could be challenged as arbitrary and capricious under the Administrative Procedure Act.

Response to Comment #3: The EPA agrees with the commenters regarding the importance of the West Mojave Desert timely addressing and attaining

the 2015 ozone NAAQS. Nonetheless, the 2008 ozone NAAQS remain in effect for all areas, and the Western Mojave Desert remains subject to planning obligations for these standards, in addition to its new and overlapping obligations for the more stringent 2015 ozone NAAQS. Therefore, we disagree that the State must revise the 2016 WMD Attainment Plan to address the 2015 ozone NAAQS.

As described in the proposed rule, under CAA section 109, the EPA promulgates primary and secondary NAAQS for pervasive air pollutants such as ozone, and periodically reviews these NAAQS to determine whether to revise them or to establish new standards.³⁸ Under CAA section 110, states with nonattainment areas must submit SIP revisions to attain these NAAQS, and to meet other requirements based on nonattainment classification. When EPA revises a NAAQS to lower the level of the standard, the previous NAAQS remain in effect until revoked; after a NAAQS is revoked, areas designated nonattainment for that NAAQS remain subject to continuing applicable requirements as "anti-backsliding" obligations.³⁹

The proposed rule describes the requirements for the 2008 ozone NAAQS, and how the 2016 WMD Attainment Plan satisfies the obligations of the West Mojave Desert as a Severe-15 nonattainment area for this standard, including the obligation to demonstrate attainment of the 2008 NAAQS by no later than July 20, 2027. The EPA's subsequent promulgation of the 2015 ozone NAAQS does not relieve the area from these obligations for the 2008 ozone NAAQS. Similarly, the EPA's approval of the 2016 WMD Attainment Plan does not relieve the area of its obligations for the 2015 ozone NAAQS. For the 2015 ozone NAAQS, California is required to submit a plan to address most elements for the West Mojave Desert by August 3, 2022, and to demonstrate attainment by no later than August 3, 2033.⁴⁰ Our approval of the 2016 WMD Attainment Plan will ensure that the attainment plan is federally enforceable as a mechanism for attaining the 2008 ozone NAAQS. Additionally, we anticipate that implementation of the West Mojave Desert control strategy for the 2008 ozone NAAQS as described in the 2016 WMD Attainment Plan will aid in the

area's attainment of the 2015 ozone NAAQS by ensuring that the area realizes consistent emissions reductions while the State undertakes planning efforts for the more stringent standards. The EPA will work with CARB and the Districts to ensure that requirements applicable to the 2015 NAAQS are addressed in a later submittal for the West Mojave Desert.

III. Final Action

No comments were submitted that change our assessment of CARB's submittals as described in our proposed action. Therefore, for the reasons discussed in detail in the proposed rule and summarized herein, under CAA section 110(k)(3), the EPA is taking final action to approve as a revision to the California SIP the following portions of the 2016 WMD Attainment Plan for the 2008 ozone NAAQS, submitted by CARB on June 2, 2017, and the 2018 SIP Update, submitted on December 11, 2018:

- Base year emissions inventory element in the 2016 WMD Attainment Plan as meeting the requirements of CAA sections 172(c)(3) and 182(a)(1) and 40 CFR 51.1115;
- Emissions statement element in the 2016 WMD Attainment Plan as meeting the requirements of CAA section 182(a)(3)(B) and 40 CFR 51.1102;
- RACM demonstration element in the 2016 WMD Attainment Plan, as meeting the requirements of CAA section 172(c)(1) and 40 CFR 51.1112(c);
- Attainment demonstration element in the 2016 WMD Attainment Plan as meeting the requirements of CAA section 182(c)(2)(A) and 40 CFR 51.1108;
- RFP demonstration element in the 2018 SIP Update as meeting the requirements of CAA sections 172(c)(2), 182(b)(1), and 182(c)(2)(B), and 40 CFR 51.1110(a)(2)(ii);
- VMT emissions offset demonstration element in the 2016 WMD Attainment Plan as meeting the requirements of CAA section 182(d)(1)(A) and 40 CFR 51.1102; and
- Motor vehicle emissions budgets in the 2018 SIP Update for the 2020 and 2023 RFP milestone year and the 2026 attainment year because they are consistent with the RFP and attainment demonstrations approved herein and meet the other criteria in 40 CFR 93.118(e).

percent of total off-road emissions). Values for 2012 are from the CARB Staff Report, Appendix A-2, and values from 2018 SIP Update.

³⁶ California Health and Safety Code Title 13, Division 3, Chapter 9, Article 3, Section 2413, was approved as a Clean Air Act waiver measure, 79 FR 6584 (February 4, 2014), and as a revision to the California SIP, 81 FR 39424 (June 16, 2016).

³⁷ California Health and Safety Code Title 13, Division 3, Chapter 9, Article 3, Section 2412, was approved as a Clean Air Act waiver measure, 79 FR 6584 (February 4, 2014), and as a revision to the California SIP, 81 FR 39424 (June 16, 2016).

³⁸ See 88 FR at 24810.

³⁹ See, e.g., 40 CFR 51.1105 (anti-backsliding obligations for 1-hour and 1997 ozone NAAQS).

⁴⁰ See 40 CFR 51.1303(a) and 51.1308(b). The EPA designated the West Mojave Desert as nonattainment for the 2015 ozone NAAQS effective August 3, 2018. 83 FR 25776 (June 4, 2018).

TABLE 1—TRANSPORTATION CONFORMITY BUDGETS FOR 2020 FOR THE 2008 OZONE NAAQS IN THE WEST MOJAVE DESERT

[Average summer weekday, tpd]^a

Budget year	VOC	NO _x
2020	3.7	8.4
2023	3.3	4.6
2026	3.0	4.2

^aSource: Table VI-3 from the 2018 SIP Update.

We are also taking final action to find that the:

- 2020 budgets from the 2018 SIP Update (Table 1) are adequate for transportation conformity purposes;⁴¹
- Clean fuels fleet program element in the 2016 WMD Attainment Plan meets the requirements of CAA sections 182(c)(4)(A) and 246 and 40 CFR 51.1102 for the 2008 ozone NAAQS; and
- Enhanced monitoring element in the 2016 WMD Attainment Plan meets the requirements of CAA section 182(c)(1) and 40 CFR 51.1102 for the 2008 ozone NAAQS.

With respect to the budgets, we are taking final action to limit the duration of our approval to last only until the effective date of the EPA's adequacy finding for any subsequently submitted budgets. We are doing so at CARB's request and in light of the benefits of using EMFAC2017-derived budgets⁴² prior to our taking final action on the future SIP revision that includes the updated budgets.

As described above, the proposed rule also proposed to conditionally approve, under CAA section 110(k)(4), the contingency measure element of the 2016 WMD Attainment Plan as meeting the requirements of CAA sections 172(c)(9) and 182(c)(9) for RFP and attainment contingency measures. Following publication of the proposed rule, the Ninth Circuit Court of Appeals issued a decision in *Association of Irrigated Residents v. U.S. Environmental Protection Agency*, which remanded the EPA's conditional approval of contingency measures for another California nonattainment area.⁴³ Based on this decision, we are deferring

final action on the contingency measure element.

Finally, we are amending the regulatory text at 40 CFR 52.220(c)(514) to identify the submittal date for the 2018 SIP Update as December 11, 2018, the date that the submittal was electronically received through the State Planning Electronic Collaboration System. The current regulatory text identifies the submittal date as December 5, 2018, which is the date of the CARB cover letter accompanying the submittal.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would

be inconsistent with the Clean Air Act; and

- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 26, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

⁴¹ Pursuant to 40 CFR 93.118(f)(2)(iii), the EPA's adequacy determination is effective upon publication of this final rule in the **Federal Register**.

⁴² On August 15, 2019, the EPA approved and announced the availability of EMFAC2017, the latest update to the EMFAC model for use by state and local governments to meet CAA requirements. See 84 FR 41717 (August 15, 2019).

⁴³ *Association of Irrigated Residents v. U.S. Environmental Protection Agency*, No. 19-71223 (9th Cir. Aug. 26, 2021).

Dated: September 18, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

For the reasons stated in the preamble, the EPA amends chapter I, title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by revising paragraph (c)(514) introductory text and adding paragraphs (c)(514)(ii)(A)(9) and (c)(563) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(514) The following plan was submitted on December 11, 2018, by the Governor's designee as an attachment to a letter dated December 5, 2018.

* * * * *

(ii) * * *

(A) * * *

(9) 2018 Updates to the California State Implementation Plan, adopted on October 25, 2018, chapter VI ("SIP Elements for the Western Mojave Desert"), and pages A-19 through A-22 of Appendix A ("Nonattainment Area Inventories").

* * * * *

(563) The following plan was submitted on June 2, 2017 by the Governor's designee.

(i) [Reserved]

(ii) *Additional materials.* (A) California Air Resources Board

(1) CARB Review of the Mojave Desert AQMD and Antelope Valley AQMD Federal 75 ppb Ozone Attainment Plans for the Western Mojave Desert Nonattainment Area, released April 21, 2017.

(2) [Reserved]

(B) Antelope Valley Air Quality Management District.

(1) AVAQMD Federal 75 ppb Ozone Attainment Plan (Western Mojave Desert Nonattainment Area), adopted on March 21, 2017, except the following portions: Chapter 2—Emission Inventories; "Reasonable Further Progress Requirements," including Table 3 (pages 18–20); "Conformity Budgets" (page 21); "Transportation Conformity," including Table 4 (pages 21–23); Appendix A—Base Year

Emission Inventory; and Appendix B—Future Year Emission Inventories.

(2) [Reserved]

(C) Mojave Desert Air Quality Management District

(1) MDAQMD Federal 75 ppb Ozone Attainment Plan (Western Mojave Desert Nonattainment Area), adopted on February 27, 2017, except the following portions: Chapter 2—Emission Inventories; "Reasonable Further Progress Requirements," including Table 3 (pages 20–22); "Conformity Budgets" (page 23); "Transportation Conformity," including Table 4 (pages 23–25); Appendix A—Base Year Emission Inventory; and Appendix B—Future Year Emission Inventories.

(2) [Reserved]

* * * * *

■ 3. Section 52.244 is amended by adding paragraph (a)(13) to read as follows:

§ 52.244 Motor vehicle emissions budgets.

(a) * * *

(13) West Mojave Desert, approved October 27, 2021.

* * * * *

[FR Doc. 2021–20618 Filed 9–24–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 84

Approval of Respiratory Protective Devices

CFR Correction

■ In Title 42 of the Code of Federal Regulations, Public Health, Parts 1 to 399, revised as of October 1, 2020, "Appendix A to Part 84—Annual (Fixed) Respirator Certification Fees", and "Appendix B to Part 84—Application-Based Respirator Certification Fees", published on pages 690 through 696, in Title 42 of the Code of Federal Regulations, Public Health, Parts 1 to 399, revised as of October 1, 2019, are reinstated.

[FR Doc. 2021–21061 Filed 9–24–21; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 371

Brokers of Property

CFR Correction

■ In Title 49 of the Code of Federal Regulations, Transportation, Parts 300 to 399, revised as of October 1, 2020, on page 78, in section 371.111, the word "paper" is removed from the first sentence.

[FR Doc. 2021–21058 Filed 9–24–21; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

Fisheries of the Exclusive Economic Zone Off Alaska

CFR Correction

■ In title 50 of the Code of Federal Regulations, Part 660 to end, revised as of October 1, 2020, on page 702, in section 679.22, the paragraph heading for paragraph (a)(7)(i) is reinstated to read as follows:

§ 679.22 Closures.

(a) * * *

(7) * * *

(i) *Bogoslof area—*

* * * * *

[FR Doc. 2021–21060 Filed 9–24–21; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

Fisheries of the Exclusive Economic Zone Off Alaska

CFR Correction

■ In title 50 of the Code of Federal Regulations, Part 660 to end, revised as of October 1, 2020, on page 637, in section 679.7, paragraph (a)(13)(ii)(A) is reinstated to read as follows:

§ 679.7 Closures

(a) * * *

(13) * * *

(ii) * * *

(A) Cutting the gangion.

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[FR Doc. 2021–21059 Filed 9–24–21; 8:45 am]

BILLING CODE 0099–10–P

Proposed Rules

Federal Register

Vol. 86, No. 184

Monday, September 27, 2021

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.

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1240

RIN 2590–AB17

Enterprise Regulatory Capital Framework Rule—Prescribed Leverage Buffer Amount and Credit Risk Transfer

AGENCY: Federal Housing Finance Agency.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: The Federal Housing Finance Agency (FHFA or the Agency) is seeking comments on a notice of proposed rulemaking (proposed rule) that would amend the Enterprise Regulatory Capital Framework (ERCF) by refining the prescribed leverage buffer amount (PLBA or leverage buffer) and credit risk transfer (CRT) securitization framework for the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac, and with Fannie Mae, each an Enterprise). The proposed rule would also make technical corrections to various provisions of the ERCF that was published on December 17, 2020.

DATES: Comments must be received on or before November 26, 2021.

ADDRESSES: You may submit your comments on the proposed rule, identified by regulatory information number (RIN) 2590–AB17, by any one of the following methods:

- *Agency Website:* www.fhfa.gov/open-for-comment-or-input.

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. If you submit your comment to the Federal eRulemaking Portal, please also send it by email to FHFA at RegComments@fhfa.gov to ensure timely receipt by FHFA. Include the following information in the subject line of your submission: Comments/RIN 2590–AB17.

- *Hand Delivered/Courier:* The hand delivery address is: Clinton Jones, General Counsel, Attention: Comments/RIN 2590–AB17, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. Deliver the package at the Seventh Street entrance Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.

- *U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service:* The mailing address for comments is: Clinton Jones, General Counsel, Attention: Comments/RIN 2590–AB17, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. Please note that all mail sent to FHFA via U.S. Mail is routed through a national irradiation facility, a process that may delay delivery by approximately two weeks. For any time-sensitive correspondence, please plan accordingly.

FOR FURTHER INFORMATION CONTACT:

Andrew Varrieur, Senior Associate Director, Office of Capital Policy, (202) 649–3141, Andrew.Varrieur@fhfa.gov; Christopher Vincent, Senior Financial Analyst, Office of Capital Policy, (202) 649–3685, Christopher.Vincent@fhfa.gov; or James Jordan, Associate General Counsel, Office of General Counsel, (202) 649–3075, James.Jordan@fhfa.gov. These are not toll-free numbers. The telephone number for the Telecommunications Device for the Deaf is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Comments

FHFA invites comments on all aspects of the proposed rule. Copies of all comments will be posted without change and will include any personal information you provide, such as your name, address, email address, and telephone number, on the FHFA website at <https://www.fhfa.gov>. In addition, copies of all comments received will be available for examination by the public through the electronic rulemaking docket for this proposed rule also located on the FHFA website.

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I. Introduction

FHFA is seeking comments on amendments to the ERCF that would refine the leverage buffer and the risk-based capital treatment for CRT transactions. The proposed amendments would better reflect the risks inherent in the Enterprises' business models and encourage the Enterprises to distribute acquired credit risk to private investors rather than to buy and hold that risk. The dynamic PLBA considered in this proposed rule is intended to achieve FHFA's objective stated in the ERCF of having the Enterprises' leverage capital requirements provide a credible backstop to risk-based capital requirements. Linking the PLBA to the ERCF's stability capital buffer, in conjunction with the proposed rule's refinements to the ERCF's CRT securitization framework, would enhance the safety and soundness of the Enterprises by removing inappropriate capital disincentives to the Enterprises to transfer risk.

FHFA adopted the ERCF on December 17, 2020 (85 FR 82150), with the purpose of implementing a going-concern regulatory capital standard to ensure that each of Fannie Mae and Freddie Mac operates in a safe and sound manner and is positioned to fulfill its statutory mission to provide stability and ongoing assistance to the secondary mortgage market across the economic cycle. In doing so, the ERCF accomplished a statutory requirement that FHFA establish by regulation risk-based capital requirements to safeguard the Enterprises against the risks that arise in the operation and management of their businesses, and implemented a new leverage framework that included both a minimum requirement and a leverage buffer. The ERCF became effective on February 16, 2021.

The ERCF evolved from FHFA's proposals for Enterprise Regulatory Capital Frameworks in 2018 and 2020, which were based on the FHFA Conservatorship Capital Framework (CCF) established in 2017. The ERCF successfully addressed issues identified through the notice and comment process on the pro-cyclicality of the proposed risk-based capital requirements, the quality of Enterprise capital used to meet the capital

requirements, and the quantity of capital requirements.

However, FHFA is concerned that certain aspects of the ERCF might create disincentives in the Enterprises' CRT programs that may result in taxpayers bearing excessive undue risk for as long as the Enterprises are in conservatorships and excessive risk to the housing finance market both during and after conservatorships. This concern is heightened by the fact that the Enterprises presently are severely undercapitalized and lack the resources on their own to safely absorb the credit risk associated with their normal operations. In conservatorships, the Enterprises are supported by Senior Preferred Stock Purchase Agreements¹ (PSPAs) between the U.S. Department of the Treasury (the Treasury) and each Enterprise, through FHFA as its conservator. Until recently, the PSPAs significantly limited the Enterprises' ability to hold capital, and only in January 2021 were the upper bounds on retained capital removed. During this period where the Enterprises are building capital, the taxpayers continue to be at heightened risk through potential PSPA draws in the event of a significant stress to the housing sector. The Enterprises have developed their CRT programs over the last several years under FHFA's oversight through guidelines, instructions, strategic plans, and scorecard objectives. FHFA views the transfer of risk, particularly credit risk, to a broad set of investors as an important tool to reduce taxpayer exposure to the risks posed by the Enterprises and to mitigate systemic risk caused by the size and monoline nature of the Enterprises' businesses. If the Enterprises were to substantially shrink their risk transfer programs for an extended period, either in response to regulatory policies or macroeconomic conditions, potential taxpayer exposure and systemic risk may increase as a result.

The refinements in this proposal would lessen the potential deterrents to Enterprise risk transfer. Specifically, the proposed rule would amend the ERCF to:

- Replace the fixed PLBA equal to 1.5 percent of an Enterprise's adjusted total

assets with a dynamic PLBA equal to 50 percent of the Enterprise's stability capital buffer as calculated in accordance with 12 CFR 1240.400;

- Replace the prudential floor of 10 percent on the risk weight assigned to any retained CRT exposure with a prudential floor of 5 percent on the risk weight assigned to any retained CRT exposure; and
- Remove the requirement that an Enterprise must apply an overall effectiveness adjustment to its retained CRT exposures in accordance with the ERCF's securitization framework in 12 CFR 1240.44(f) and (i).

The proposed rule would also make technical corrections to various provisions of the ERCF that was published on December 17, 2020.

The PSPAs between the Treasury and each Enterprise, through FHFA as its conservator, as amended by letter agreements executed by the parties on January 14, 2021,² include a covenant at section 5.15 which states: "[The Enterprise] shall comply with the Enterprise Regulatory Capital Framework [published in the **Federal Register** at 85 FR 82150 on December 17, 2020] disregarding any subsequent amendment or other modifications to that rule." Modifying that covenant will require agreement between the Treasury and FHFA under section 6.3 of the PSPAs.

II. Background and Rationale for the Proposed Rule

A. PLBA

Background

The ERCF requires an Enterprise to maintain a leverage ratio of tier 1 capital to adjusted total assets of at least 2.5 percent. In addition, to avoid limits on capital distributions and discretionary bonus payments, an Enterprise must also maintain a fixed tier 1 capital PLBA equal to at least 1.5 percent of adjusted total assets.

The primary purpose of the combined leverage requirement and PLBA is to serve as a non-risk-based supplementary measure that provides a credible backstop to the combined risk-based capital requirements and prescribed capital conservation buffer amount (PCCBA), where the PCCBA comprises the stability capital buffer, the stress capital buffer, and the countercyclical capital buffer. This type of simple,

transparent, and independent measure of risk provides an important safeguard against model risk and measurement error in the risk-based capital requirements and acquisition strategies of the Enterprises. FHFA's rationale for the leverage requirement and buffer is consistent with that of U.S. and international banking regulators, although the size of each regulator's leverage buffer varies by regulatory regime. In the U.S., large banking organizations must maintain an enhanced supplementary leverage ratio (eSLR) of 2 percent of total leverage exposure on top of their 3 percent supplementary leverage ratio (SLR) to avoid restrictions on distributions and discretionary bonuses. Internationally, systemically important banks are required to hold a leverage buffer that varies by the bank's systemic importance.

The Enterprises are chartered to fulfill a countercyclical role in the housing finance market. The COVID-19 pandemic, while unique and not the basis for this proposed rule, has effectively illustrated why a dynamic leverage buffer may be appropriate for the Enterprises. During the pandemic, as many mortgage market participants pulled back from the market due to capital and liquidity constraints, the Enterprises stepped in to fulfill their countercyclical role, leading to greater reliance on Enterprise execution for conforming mortgages. This, combined with the Board of Governors of the Federal Reserve System's (Federal Reserve) monthly purchases of \$40 billion in Agency mortgage-backed securities (MBS), caused the Enterprises' balance sheets to expand considerably. As a result, the PLBA represents an increasingly large component of the Enterprises' capital requirements and capital buffers relative to when FHFA calibrated the PLBA in 2019. In addition, the combined leverage requirement and PLBA exceeds the combined risk-based capital requirement and PCCBA at some level for both Enterprises. The leverage requirement and current PLBA are based on adjusted total assets, which is a relatively stable measure over time. Given this calibration, FHFA expects the current relationships between leverage and risk-based capital at the Enterprises will continue for the foreseeable future. When leverage capital is consistently the binding capital constraint, it provides an incentive for an institution to increase risk taking because taking on more risk is not reflected in commensurately higher capital requirements, while

¹ Fannie Mae's Amended and Restated Senior Preferred Stock Purchase Agreement with Treasury (September 26, 2008), https://www.fhfa.gov/Conservatorship/Documents/Senior-Preferred-Stock-Agree/FNM/SPSPA-amends/FNM-Amended-and-Restated-SPSPA_09-26-2008.pdf; Freddie Mac's Amended and Restated Senior Preferred Stock Purchase Agreement with Treasury (September 26, 2008), https://www.fhfa.gov/Conservatorship/Documents/Senior-Preferred-Stock-Agree/FRE/SPSPA-amends/FRE-Amended-and-Restated-SPSPA_09-26-2008.pdf.

² 2021 Fannie Mae Letter Agreement (January 14, 2021), <https://home.treasury.gov/system/files/136/Executed-Letter-Agreement-for-Fannie-Mae.pdf>; 2021 Freddie Mac Letter Agreement (January 14, 2021), <https://home.treasury.gov/system/files/136/Executed-Letter-Agreement-for-Freddie%20Mac.pdf>.

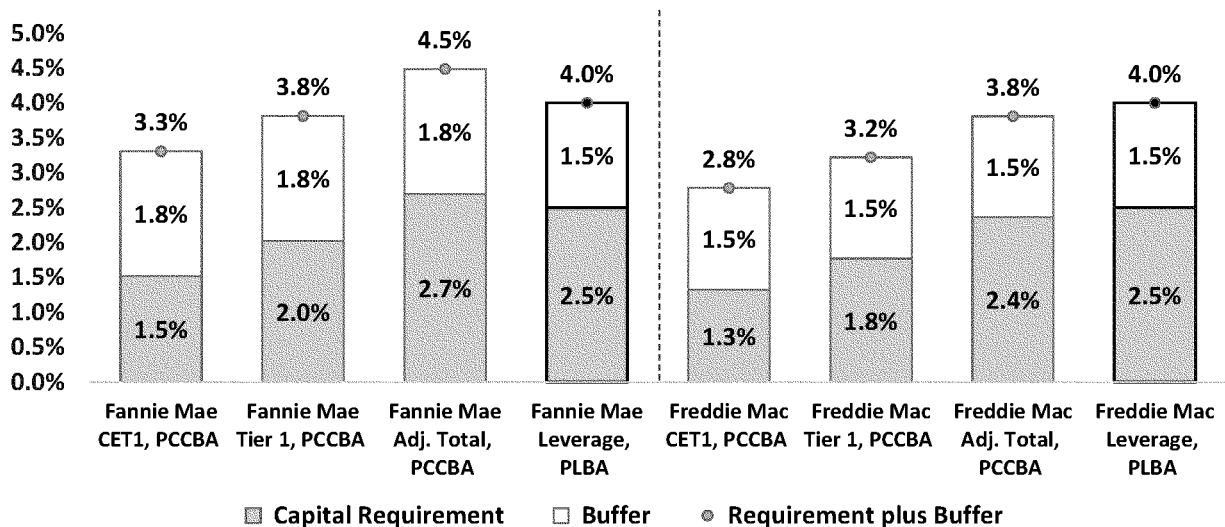
greater risk may generate greater returns. When leverage capital sufficiently exceeds risk-based capital, high risk exposures and low risk exposures have the same capital requirements, so an Enterprise has an incentive to acquire higher-risk, higher-yielding mortgages, all else equal.

As of March 31, 2021, Fannie Mae's tier 1 leverage capital requirement plus PLBA of 4 percent was the binding capital constraint relative to their estimated common equity tier 1 (CET1)

capital requirement plus PCCBA of 3.3 percent and their estimated tier 1 risk-based capital requirement plus PCCBA of 3.8 percent, all relative to adjusted total assets. Fannie Mae's estimated adjusted total capital requirement plus PCCBA of 4.5 percent (relative to adjusted total assets) was their only risk-based capital requirement that exceeded their leverage capital requirement plus PLBA. At Freddie Mac, the leverage capital requirement plus PLBA was the binding capital constraint relative to

every risk-based capital metric. Freddie Mac's estimated CET1 capital requirement plus PCCBA of 2.8 percent, estimated tier 1 risk-based capital requirement plus PCCBA of 3.2 percent, and estimated adjusted total capital requirement plus PCCBA of 3.8 percent, all relative to adjusted total assets, were each smaller than their tier 1 leverage capital requirement plus PLBA of 4 percent.

Figure 1: Estimated Enterprise Capital Requirements and Buffers relative to Adjusted Total Assets, as of March 31, 2021



For the Enterprises combined, the tier 1 leverage capital requirement plus PLBA was approximately 12 percent larger than the combined tier 1 risk-based capital requirement plus PCCBA (relative to adjusted total assets) as of March 31, 2021. This excess of total leverage capital over tier 1 risk-based capital has grown from 10 percent when FHFA calibrated the ERCF near the end of 2019—a 20 percent increase in only two years. The leverage requirement and PLBA are met with tier 1 capital, while the tier 1 risk-based capital requirement and PCCBA are met with tier 1 capital and CET1 capital respectively, which allows for the most direct comparison of leverage capital to risk-based capital. In addition, CET1 capital and tier 1 capital represent the highest quality and second-highest quality forms of capital, respectively, so examining the binding nature of the tier 1 leverage requirement relative to the tier 1 risk-based capital requirement is prudent when

considering the safety and soundness of the Enterprises.

Rationale for Revisiting the PLBA

The primary purpose of the ERCF's leverage requirement and PLBA is to serve as a credible backstop to the risk-based capital requirements and risk-based capital buffers. This is consistent with the stated purpose of the SLR and eSLR in the U.S. banking framework.³ FHFA is proposing a recalibration of the PLBA because a leverage ratio that exceeds risk-based capital requirements throughout the economic cycle could lead to undesirable outcomes at the

³ In a June 2021 Federal Open Market Committee press conference, the Federal Reserve Chairman stated: "Our position has been for a long time, and it is now, that we'd like the leverage ratio to be a backstop to risk-based capital requirements. When leverage requirements are binding it does skew incentives for firms to substitute lower-risk assets for high-risk ones." See https://www.federalreserve.gov/mediacenter/files/FOMC_presconf20210616.pdf.

Enterprises, including promoting risk-taking and creating disincentives for CRT and other forms of risk transfer. Evolutions in the international and U.S. banking frameworks and public comments on FHFA's 2020 re-proposed capital rule support the proposed PLBA recalibration.

Financial regulators and policymakers have consistently investigated ways to lower the quantity of leverage required for banks, with a specific focus on the SLR and eSLR. In the U.S., banking regulators require global systemically important banks (GSIBs) to hold tier 1 capital in excess of 5 percent of total on-and-off balance sheet assets (measured using total leverage exposure, which is comparable to adjusted total assets at the Enterprises) consisting of a 3 percent minimum SLR and a 2 percent leverage buffer (the eSLR). Internationally, Basel III standards require systemically important banks to hold a tier 1 capital leverage ratio buffer in excess of a 3

percent leverage requirement equal to 50 percent of a GSIB's higher loss-absorbency risk-based requirements. This dynamic leverage buffer tailors leverage requirements to business activities and risk profiles, aiming to retain a meaningful calibration of leverage ratio standards while not discouraging firms from participating in low-risk activities. The higher loss-absorbency risk-based requirements is a measure similar to the U.S. banking framework's GSIB surcharge, which varies in size depending on a bank's systemic importance, as measured using a bank's size, interconnectedness, cross-jurisdictional activity, substitutability, complexity, and use of short-term wholesale funding. In April 2018, the Federal Reserve and the Office of the Comptroller of the Currency (OCC) released a similar proposal that would tailor the eSLR for GSIBs by modifying the fixed 2 percent eSLR buffer to equal one half of each firm's GSIB capital surcharge.⁴ This proposal would have a significant impact on the leverage ratios of U.S. GSIBs, decreasing the fixed 2 percent eSLR to, on a median basis, approximately 1.25 percent.

In addition, there have been various proposals in recent years from the U.S. Department of the Treasury and the U.S. Congress for a more targeted approach to removing certain items from total leverage exposure to address the negative externalities the SLR and eSLR requirements may have on market liquidity and low-risk assets. One such proposal included adjustments to the calibration of the eSLR and the leverage exposure calculation to exclude from the denominator of total leverage exposure cash on deposit with central banks, U.S. Treasury securities, and initial margin for centrally cleared derivatives.⁵ The Economic Growth, Regulatory Relief, and Consumer Protection Act of 2018⁶ adopted part of the Treasury's recommendation by relaxing the leverage ratio for "custodial banks" by removing funds held at central banks from the leverage ratio's denominator. Furthermore, as FHFA did in the ERCF, there is precedent for bank regulators tailoring the leverage ratio to conform to an institution's unique circumstances. As an example, in 2015, the Federal Reserve reduced the eSLR requirement for GE Capital from 5 percent to 4 percent when it was designated a nonbank systemically

important financial institution (SIFI) by the Financial Stability Oversight Council (FSOC).⁷

The regulatory focus on reevaluating bank leverage ratio requirements has sharpened further during the COVID-19 pandemic. In March 2020, to stabilize dislocations in the market for U.S. Treasuries as a result of the pandemic, the Federal Reserve temporarily modified the SLR to exclude U.S. Treasury securities and central bank reserves from the leverage calculation. In March 2021, the Federal Reserve allowed this temporary relief to expire as the strains in the Treasury market resulting from COVID-19 had eased, but acknowledged it "may need to address the current design and calibration of the SLR over time to prevent strains from developing that could both constrain economic growth and undermine financial stability."⁸ After allowing the temporary relief to expire, the leverage ratio became the binding capital constraint for JPMorgan Chase & Co., the largest GSIB. The Federal Reserve also stated that "to ensure that the SLR—which was established in 2014 as an additional capital requirement—remains effective in an environment of higher reserves, the Board will soon be inviting public comment on several potential SLR modifications."⁹ Further, members of the Federal Reserve's Board of Governors recently confirmed that the Board is looking to make changes to the leverage framework.¹⁰

The current circumstances in which tier 1 leverage capital requirements are binding for both Fannie Mae and Freddie Mac may lead to perverse incentives that have the Enterprises take on more risk than is prudent. By treating all risk similarly, a binding leverage ratio driven by the PLBA may incentivize risk-taking because the capital requirement would be the same for high-risk and low-risk loans. In addition, the Enterprises would have no capital incentive to transfer risk to achieve a risk-based capital requirement lower than their leverage requirement. However, when risk-based capital requirements are higher than leverage capital requirements, CRT represents a viable way to both lower risk at the Enterprises and to shrink the gap

between capital requirements and available capital, promoting safety and soundness. These were pressing issues to commenters when FHFA re-proposed its Enterprise capital rule in 2020.

Prior to finalizing the ERCF, FHFA received a significant number of public comments on FHFA's proposed PLBA. Some commenters recommended a leverage buffer smaller than was proposed (both with and without corresponding recommendations for the leverage requirement). Most commenters focused on the size of the combined leverage requirement and PLBA as a single 4 percent leverage ratio. Most of those commenters recommended a combined leverage ratio smaller than 4 percent. Some suggested that 4 percent overstates potential risk in the Enterprises' books because FHFA's ERCF calibration was based on historical losses without adjusting for prevailing portfolio composition. That is, given that the Enterprises are no longer permitted to acquire many of the loans that precipitated the 2008 financial crisis, such as Alt-A loans and option ARMs, a leverage ratio corresponding to the Enterprises' current acquisition profile should not be calibrated to losses involving such loans. Relatedly, commenters suggested that concerns the Enterprises may again loosen underwriting standards have been addressed in several ways, including through post-crisis statutory and regulatory changes such as the Qualified Mortgage and Ability-to-Repay rule, which would require a statutory change and/or a notice of proposed rulemaking followed by a period of public comment in order to modify. In addition, commenters argued that these concerns were further addressed through post-crisis improvements in risk management and improved loss-mitigation capabilities, incorporation of automated tools into the underwriting process to verify the accuracy of data and detect loan manufacturing defects, tightened counterparty risk management, and improvements in fraud prevention.

Commenters also suggested that the Enterprises' recent Dodd-Frank Act Stress Tests (DFAST) results do not support a 4 percent leverage ratio. Commenters' analysis at the time indicated that 4 percent leverage would be between four and thirteen times DFAST losses, depending on which scenario was being compared. Commenters suggested this multiple was excessive. In addition, some commenters viewed the PLBA as being duplicative of other ERCF adjustments and buffers that also were designed to mitigate model and related risk. Finally,

⁷ <https://www.govinfo.gov/content/pkg/FR-2015-07-24/pdf/2015-18124.pdf>.

⁸ <https://www.federalreserve.gov/newsevents/pressreleases/bcreg20210319a.htm>.

⁹ *Id.*

¹⁰ In May 2021, the Board's Vice Chair for Supervision testified to the U.S. House Financial Services Committee: "Among other measures, we are reviewing the design and calibration of the supplementary leverage ratio. . . ." See <https://www.federalreserve.gov/newsevents/testimony/quarles20210519a.htm>.

⁴ <https://www.federalreserve.gov/newsevents/pressreleases/bcreg20180411a.htm>.

⁵ <https://www.treasury.gov/press-center/news/Pages/Summary-of-Recommendations-for-Regulatory-Reform.aspx>.

⁶ Public Law 115–174, 132 Stat. 1296 (2018).

as stated above, many commenters stated that a binding leverage ratio would be a disincentive for CRT and encourage the Enterprises to take on more risk.

B. CRT

Background

The Enterprises' core businesses reflect the acquisition of mortgages from financial institutions and the bundling of those mortgages into collateral for MBS. The Enterprises sell to investors part of the cash flows that stem from the mortgages underlying the MBS. The Enterprises guarantee the principal and interest payments to investors and collect a guarantee fee from their sellers.

Mortgage exposures typically carry both interest rate and credit risk. In general, the Enterprises transfer mortgage interest rate risk and retain and manage mortgage credit risk. The interest rate risk on securitized mortgages is transferred to investors through MBS sales. The Enterprises' principal and interest guarantee helps to create a liquid and efficient MBS market. It also limits the credit risk assumed by MBS investors, except for an investor's counterparty exposure to the Enterprises. Credit risk can be broadly separated into expected losses and unexpected losses, as determined by a credit model. The Enterprises rely on guarantee fees to cover expected losses and, absent CRT, equity capital to cover unexpected losses.

In its role as conservator, FHFA established a goal of reducing taxpayer risk exposure to the credit guarantees extended by the Enterprises. To accomplish this objective, FHFA used its conservatorship strategic plans and scorecards to encourage the Enterprises to transfer credit risk to the private sector. In 2012, FHFA's Strategic Plan for Enterprise Conservatorships proposed the use of loss sharing agreements to reduce the credit risk incurred by the Enterprises. The 2013 Conservatorship Scorecard required each Enterprise to "demonstrate the viability of multiple types of [credit] risk transfer transactions" on single-family loans. The Enterprises first implemented their CRT programs that same year and have since transferred to private investors a substantial amount of the credit risk of new acquisitions the Enterprises assume for loans in targeted loan categories. The programs have become a core part of the Enterprises' single-family credit guarantee business and include or have included CRTs via capital markets issuances (both corporate debt and bankruptcy remote trust structures), insurance/reinsurance

transactions, senior/subordinate transactions, and a variety of lender collateralized recourse transactions.

The 2014 Strategic Plan for the Conservatorships of Fannie Mae and Freddie Mac emphasized the desirability of greater use of CRT in the future. Additionally, the 2014 and 2015 Conservatorship Scorecards set more ambitious CRT performance goals for each Enterprise. Since that time, the Conservatorship Scorecards have included various goals to ensure the continued use of CRT as a means of reducing risk exposure to taxpayers. For example, the 2016 through 2019 Conservatorship Scorecards established an objective for the Enterprises to transfer a meaningful portion of credit risk on at least 90 percent of the unpaid principal balance (UPB) of their acquired single-family mortgage loans targeted for credit risk transfer. Targeted loans include fixed-rate, non-HARP loans with terms over 20 years and loan-to-value (LTV) ratios above 60 percent. Such loans represent a substantial amount of the credit risk associated with all new loan acquisitions.

From the beginning of the Enterprises' single-family CRT programs in 2013 through the end of 2020, Fannie Mae and Freddie Mac have transferred a portion of credit risk on approximately \$4.1 trillion of UPB, with a combined risk-in-force (RIF) of about \$137 billion, or 3.3 percent of UPB.¹¹

The Enterprises' CRT programs have evolved over time in response to changing macroeconomic conditions, loan acquisition risk profiles, and views of expected and unexpected losses. However, across the different types of CRT vehicles, the basic transaction is the same: An Enterprise pays private market participants to assume credit risk in a severe stress scenario on mortgages the Enterprise guarantees, where the severe stress scenario is generally comparable to the 2008 global financial crisis. Further, to ensure alignment of interests with investors, the Enterprises retain at least 5 percent of the risk exposure sold in their CRT transactions. This is referred to as vertical risk retention.

The Enterprises have developed their various CRT products in order to meet certain program goals established by FHFA in 2012. Among these goals is that CRT transactions should be economically sensible, repeatable, scalable, and structured to not disrupt the efficient operation of the "To Be Announced" (TBA) market (which

provides the market with benefits including allowing borrowers to lock in rates in advance of closing). The widespread use of TBA trading has contributed significantly to the liquidity and efficiency of the secondary market for single-class MBS. A misconception is that "economically sensible" implies low-cost on an absolute basis. However, the costs of CRT should be evaluated relative to the cost of equity capital needed to self-insure the risk. To be economically sensible, an Enterprise should consider executing CRT transactions when the cost to the Enterprise for transferring the credit risk does not meaningfully exceed the cost to the Enterprise of self-insuring the credit risk being transferred. Market conditions in addition to a transaction's cost and structure ultimately determine a CRT's relative profitability, but if CRT premium payments are low relative to the capital reduction provided by the CRT, then the Enterprise has the opportunity to execute economically sensible CRT transactions, and CRT may provide taxpayer protection at a lower cost than equity capital.

A further goal was to develop different types of products to provide for the broadest possible access to investors with the expectation that at least some of those investors would remain in the market through all phases of a housing price cycle. Since the inception of the programs in 2013, the types of single-family CRT transactions have included structured capital markets issuances known as Structured Agency Credit Risk (STACR) for Freddie Mac and Connecticut Avenue Securities (CAS) for Fannie Mae, insurance/reinsurance transactions known as Agency Credit Insurance Structure (ACIS) for Freddie Mac and Credit Insurance Risk Transfer (CIRT) for Fannie Mae, front-end lender risk sharing transactions, and senior/subordinate transactions.

Most of the RIF has come from capital markets issuances (STACR and CAS). These securities were initially issued as direct debt obligations of each Enterprise; however, in 2018, both Enterprises transitioned their capital markets CRT issuances to a Trust structure with the notes being issued by a bankruptcy remote trust created for each individual CAS or STACR transaction. The proceeds from the sale of the notes are deposited into the bankruptcy remote trust and there is no direct counterparty exposure to the Enterprises for investors. By implementing the Trust structure, the Enterprises are now able to benefit from insurance accounting treatment for their capital markets CRT transactions.

¹¹ Credit Risk Transfer Progress Report 4Q20, <https://www.fhfa.gov/AboutUs/Reports/ReportDocuments/CRT-Progress-Report-4Q20.pdf>.

Insurance accounting treatment aligns the timing of the recognition of credit losses with CRT loss recoveries. Under the previous corporate debt structure, there was a significant timing mismatch between the recognition of losses and recoveries as the CRT benefit could not be recognized until the underlying delinquent mortgage loan had progressed through the often-lengthy disposition process.

In addition, both Fannie Mae and Freddie Mac now engage in CRT offerings under which the securities are issued by a third-party bankruptcy-remote trust that also qualifies as a Real Estate Mortgage Investment Conduit (REMIC). The transition of the capital markets CRT programs to the REMIC Trust structure was a collaborative, long-term effort between Fannie Mae, Freddie Mac, and FHFA. The REMIC Trust structure, like the trust structure described above, eliminates accounting mismatches associated with prior direct debt issuance transactions and limits investor exposure to Enterprise counterparty risk. Additionally, the REMIC structure is often more attractive to domestic Real Estate Investment Trusts (REITs) and foreign investors.

After exceptionally strong issuance volume between 2013 and the first quarter of 2020, neither Enterprise entered into new CRT transactions in the second quarter of 2020 due to the adverse market conditions stemming from the COVID-19 pandemic. However, Freddie Mac returned to the CRT capital markets and insurance/reinsurance market during the third quarter of 2020, executing nine transactions in the second half of the year. In contrast, and despite improved market conditions, Fannie Mae continued to pause issuance of new CRT transactions to evaluate the costs and benefits of CRT, including the capital relief provided by the transactions and the market conditions, as well as their overall capital requirements, risk appetite, and business plan.¹² Overall, while down from its peak in 2019, total CRT volume in 2020 remained strong and exceeded 2018 volume despite the extreme and unforeseen difficulties arising from the COVID-19 pandemic. In 2021, both Enterprises are considering potential changes to their CRT programs to optimize risk transfer and capital relief under the ERCF.

Multifamily CRT

Even before the formalization of the single-family CRT programs, risk transfer to the private sector had long

been an integral part of the multifamily business models at the Enterprises. Freddie Mac has traditionally focused on senior/subordinate structures via capital market transactions largely through its K-Deal platform. Fannie Mae has traditionally focused on pro-rata risk sharing directly with lenders through its Delegated Underwriting and Servicing (DUS) program. As the single-family CRT programs evolved and grew, the Enterprises worked to expand their existing multifamily risk transfer models to include structures similar to those of the single-family businesses.

Fannie Mae issued its first multifamily reinsurance transaction in 2016, the Multifamily Credit Insurance Risk Transfer (MCIRT), which was based on the framework of the existing single-family reinsurance (CIRT) transactions, where the Enterprise purchases insurance coverage underwritten by a group of insurers/reinsurers. Fannie Mae uses MCIRT to transfer credit risk on multifamily loan acquisitions with up to \$30 million in UPB. Since the first transaction in 2016, Fannie Mae's MCIRT has become programmatic with a total of eight transactions executed. These transactions provide combined RIF of \$1.9 billion on a total of \$81 billion (as measured at time of deal inception) of Fannie Mae's multifamily loan acquisitions.

In 2018, Freddie Mac introduced its Multifamily Credit Insurance Pool (MCIP) program to transfer additional credit risk on its multifamily loan acquisitions to the reinsurance market. In the MCIP structure, as in Fannie Mae's MCIRT program, Freddie Mac purchases insurance coverage underwritten by a group of insurers/reinsurers that generally provide first loss and/or mezzanine loss credit protection. These transactions are also similar in structure to the single-family ACIS transactions.

In 2019, Fannie Mae expanded its multifamily CRT program by executing its first Multifamily Connecticut Avenue Securities (MCAS) CRT transaction which is based on the framework for Fannie Mae's existing single-family CAS execution. Fannie Mae uses MCAS to transfer credit risk on multifamily loans with UPBs greater than \$30 million. However, this new product allowed Fannie Mae to reach a multifamily CRT investor base outside of the reinsurance industry. Fannie Mae has executed a total of two MCAS transactions which provide combined RIF of \$0.9 billion on a total of \$29 billion (as measured at time of deal inception) of Fannie Mae's multifamily loan acquisitions.

Freddie Mac's multifamily capital markets CRT program began with the issuance of three fixed-rate Multifamily Structured Credit Risk (MSCR) notes in 2016 and 2017 (as a separate offering from the K-deal program). These legacy MSCR notes use a fixed severity structure like early single-family CRTs and are unsecured and unguaranteed corporate debt obligations that transfer to third parties a portion of the credit risk of the multifamily loans underlying certain consolidated other securitizations and other mortgage-related guarantees. SCR Notes are synthetic instruments whose cash flows are driven by the performance of a pool of multifamily reference obligations, instead of actual collateral tied to a trust in a typical securitization such as K-Deals. In 2021, Freddie Mac's MSCR program transitioned to an actual loss/Trust structure, and coupon payments are now floating rate, indexed to the Secured Overnight Financing Rate (SOFR). These features align with the current single-family STACR CRT product.

CRT in the ERCF

The Enterprises manage mortgage credit risk through their underwriting systems, guarantee fee revenues, and CRT programs. The ERCF reflects the Enterprises' management of mortgage credit risk by allowing the Enterprises to reduce their credit risk-weighted assets for eligible CRT. However, the ERCF's treatment of CRT includes various components that limit the amount of capital relief provided by CRTs to ensure that all exposures retained by an Enterprise are meaningfully capitalized. Dollar-for-dollar capital relief should not be expected given that CRT transactions introduce counterparty and structural risk, and CRT has not yet been tested through a full economic cycle.

Under the ERCF, an Enterprise determines the capital treatment for eligible CRT by assigning risk weights to retained CRT exposures. The rule includes: (i) Operational criteria to mitigate the risk that the terms or structure of the CRT would not be effective in transferring credit risk; (ii) a tranche-specific prudential risk weight floor of 10 percent; and (iii) adjustments to reflect loss sharing effectiveness, loss-timing effectiveness, and a dynamic overall effectiveness adjustment meant to capture the differences between CRT and regulatory capital.

The operational criteria, risk weight floor, and effectiveness adjustments limit capital relief from CRT. The operational criteria act as a gateway by setting minimum criteria for potential

¹² <https://www.fanniemae.com/media/40576/display>.

CRT credit risk capital relief. The 10 percent risk weight floor adds minimum capital requirements to all retained CRT exposures, no matter how remote the credit risk. The effectiveness adjustments reduce the risk-weighted assets of transferred CRT tranches, thereby reducing the capital relief afforded by the CRT. Of these three elements included in the ERCF's CRT treatment, the risk weight floor drives the majority of the reduction in credit risk capital relief due to the relative size of the low-risk CRT exposures the Enterprises generally retain. For example, the stylized CRT transaction in FHFA's 2020 re-proposed capital rule showed capital relief of 38 percent due to the CRT.¹³ However, absent the risk weight floor on retained exposures, capital relief would have been approximately 66 percent.

Rationale for Revisiting the ERCF's CRT Treatment

CRT is an effective mechanism for distributing credit risk across a broad mix of investors and has become an integral part of the Enterprises' business models. FHFA is proposing amendments to the ERCF that would revise the CRT securitization framework for several reasons.

First, if an Enterprise retained every tranche of a CRT, its post-CRT credit risk capital requirement for the CRT exposures would be higher than its pre-CRT credit risk capital requirements for the underlying mortgage exposures due to the structural and modeling risk of the CRT itself. The capital relief afforded by the ERCF CRT securitization framework more than offsets this so-called securitization penalty, but within the securitization framework, potential capital relief is limited by adjustments that reflect various ways a CRT might be less than fully effective at transferring risk. Increasing the capital relief for CRT by reducing these effectiveness adjustments could improve the safety and soundness of each Enterprise by encouraging the transfer of risk so that each Enterprise can fulfill its statutory mission to provide stability and ongoing assistance to the secondary mortgage market across the economic cycle.

Second, FHFA believes that part of the process to responsibly end the conservatorships of the Enterprises includes the transfer of a portion of the Enterprises' credit risk to private markets. Such activity allows the Enterprises to maintain their core businesses, fulfill their statutory missions, and grow organically while simultaneously shedding risk that could

otherwise prevent them from accomplishing these goals. It is possible that in the absence of risk transfer, required capital may increase faster than retained earnings and the Enterprises may therefore grow farther from achieving capital adequacy and exiting their conservatorships. To the extent that the earnings expenses of CRT are smaller than the capital relief provided by CRT, executing CRT would help alleviate this issue.

Third, a revised risk-based capital treatment for CRT could facilitate regulatory capital planning in furtherance of the safety and soundness of the Enterprises and their countercyclical mission. The Enterprises' CRT programs, which FHFA has in the past required to cover 90 percent of the UPB of target loans (generally those with an LTV greater than 60 percent and a loan term greater than 20 years), help facilitate the continued acquisition of higher risk loans throughout the economic cycle due to capital relief afforded to risk transfer. In addition, as adopted, the ERCF's CRT framework does little to complement the single-family countercyclical adjustment. Revised CRT incentives could, for example, help to align the issuance of CRT with changes in the countercyclical adjustment.

Fourth, prior to finalizing the ERCF, FHFA received a significant number of comments on FHFA's proposed approach to CRT. Many commenters expressed the view that CRT is an effective means by which to transfer risk to private markets, protect taxpayers, and stabilize the Enterprises and the housing finance market more generally. Consequently, most of these commenters suggested that the proposed treatment of CRTs was too punitive and would imprudently discourage CRTs. Many commenters criticized the 10 percent risk weight floor and the overall effectiveness adjustment, arguing that FHFA's proposed policy choices would unduly decrease the capital relief provided by CRT and reduce the Enterprises' incentives to engage in CRT. FHFA nevertheless adopted the risk weight floor as proposed, citing a belief that 10 percent represents an appropriate capitalization for the credit risk in these retained risks and a favorable comparison to the U.S. bank regulatory framework. To account for the fact that CRT does not provide the same loss-absorbing capacity as equity financing and to reduce the extent to which the proposed 10 percent adjustment may lead to more regulatory capital than is necessary to ensure safety and soundness, FHFA adopted a

modified overall effectiveness adjustment that starts at 10 percent and decreases with an exposure's credit risk.

FHFA also received comments on the interaction of CRTs and the leverage ratio requirement. Several commenters expressed concern about the potential adverse impact of a binding leverage requirement on CRTs. Specifically, commenters indicated that a binding leverage requirement would provide no incentive for the Enterprises to lower their risk-based capital requirements and therefore would disincentivize CRTs, which could lead the Enterprises to reduce or halt their CRT programs and increase the risks held in portfolio.

III. Proposed Requirements

A. PLBA

The proposed rule would amend the ERCF by replacing the fixed PLBA equal to 1.5 percent of an Enterprise's adjusted total assets with a dynamic PLBA equal to 50 percent of the Enterprise's stability capital buffer as calculated in accordance with 12 CFR 1240.400.

The Enterprise-specific stability capital buffer was designed to mitigate risk to national housing finance markets by requiring a larger Enterprise to maintain a larger cushion of high-quality capital to reduce the likelihood of a large Enterprise's failure and preclude the potential impact a failure would have on the national housing finance markets. Such a buffer creates incentives for each Enterprise to reduce its housing finance market stability risk by curbing its market share and growth in ordinary times, preserving room for a larger role during a period of financial stress, and may offset the funding advantage that an Enterprise might have on account of being perceived as "too big to fail." The stability capital buffer is based on a market share approach, where each Enterprise's stability capital buffer is directly related to its relative share of total residential mortgage debt outstanding that exceeds a threshold of 5 percent market share. The stability capital buffer, expressed as a percent of adjusted total assets, increases by 5 basis points for each percentage point of market share exceeding that threshold.

The proposed rule would replace the fixed 1.5 percent PLBA with a dynamic leverage buffer determined annually and tied to the stability capital buffer. The stability capital buffer is an effective proxy for the U.S. banking framework's GSIB capital surcharge and the Basel higher loss-absorbency risk-based requirement as it is designed to address the predominant threat an Enterprise poses to national housing markets—its

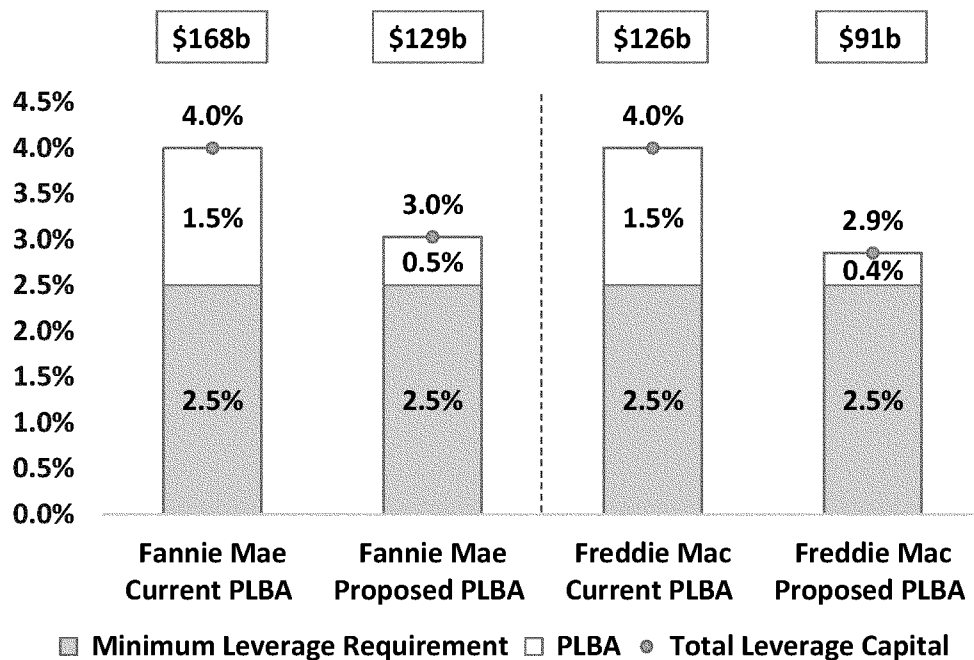
¹³ 85 FR at 39335 (June 30, 2020).

size. Thus, in a manner similar to the U.S. banking regulators' proposal to set the eSLR buffer to one-half of the GSIB surcharge, an Enterprise's PLBA would equal one-half of its stability capital buffer under the proposed rule. Under the amended rule, as shown in the

figure below and as of March 31, 2021, Fannie Mae's PLBA would decrease from approximately \$62 billion, or 1.5 percent of the prior quarter's adjusted total assets, to approximately \$23 billion, or 0.53 percent of adjusted total assets.¹⁴ Freddie Mac's PLBA would

similarly decrease from \$46 billion, or 1.5 percent of the prior quarter's adjusted total assets, to approximately \$11 billion, or 0.35 percent of adjusted total assets.¹⁵

Figure 2: Estimated Enterprise Leverage Capital under the Current ERCF and the Proposed Rule, as of March 31, 2021



There are several benefits of the proposed approach. First, decreasing the PLBA to the point where risk-based capital is the binding capital constraint at the Enterprises would promote safety and soundness by lessening the likelihood that an Enterprise has an incentive to take on more risk in a capital optimization strategy. Setting the PLBA to 50 percent of the stability capital buffer would not guarantee that leverage capital is never binding, but it would restore leverage capital to a position of a credible backstop rather than the binding capital constraint for the foreseeable future. This would allow the other aspects of the ERCF, namely the risk-based capital requirements, including the single-family countercyclical adjustment, to work as intended. For example, the single-family countercyclical adjustment works by increasing risk-based capital requirements to largely offset capital

benefits driven by house price appreciation. This effective tool alleviates concerns that risk-based capital will artificially decline with increasing property values, thereby lessening the need for a consistently binding leverage capital framework. An unduly high leverage requirement dampens the functionality of the single-family countercyclical adjustment.

The ERCF does not currently contain an exposure-level method to mitigate the pro-cyclicality of the credit risk capital requirements for multifamily mortgage exposures. FHFA has, in two notices of proposed rulemaking, indicated it would like to implement such an adjustment, and has twice sought recommendations for potential approaches. Although FHFA has received numerous suggestions for a multifamily countercyclical adjustment, most have relied on proprietary data or indices to some extent. FHFA is again

expressing its desire to include a multifamily countercyclical adjustment in the ERCF that is not reliant on proprietary information and is seeking input on how that adjustment should be constructed.

Question 1: What approach that relies only on non-proprietary data or indices should FHFA consider to mitigate the pro-cyclicality of the credit risk capital requirements for multifamily mortgage exposures?

Second, the proposed rule's PLBA will encourage the Enterprises to transfer risk rather than to buy and hold risk. Leverage capital requirements and buffers treat each dollar of exposure equally and incentivize risk-taking to the point where risk-based capital equals leverage capital. At the Enterprises, seasoned portfolios generally require less capital than new acquisitions because risk determinants such as the loan-to-value ratio typically

¹⁴ The stability capital buffer is calculated using adjusted total assets as of the most recent December 31, unless adjusted total assets at that time is greater

than adjusted total assets as of the prior December 31, in which case the calculation would use adjusted total assets from the prior December 31.

¹⁵ *Id.*

improve as mortgage loans age. Therefore, higher leverage requirements incentivize an Enterprise to acquire riskier, higher-yielding exposures and then to hold that risk so that risk-based capital on the book approximates leverage capital on the book. A lower PLBA directly encourages a risk transfer strategy by lowering the long-run risk-based capital target for an Enterprise's book. Buying and holding risky assets would likely no longer be optimal from a capital perspective if the risk-based capital on an Enterprise's seasoned portfolio exceeded leverage capital.

Third, a leverage framework with a dynamic PLBA that grows and shrinks as an Enterprise grows and shrinks, respectively, would function as a better backstop to a risk-based capital framework that includes a systemic risk component such as the stability capital buffer. In the 2020 ERCF notice of proposed rulemaking, FHFA argued that a larger Enterprise's default would pose a greater threat to the national housing finance markets than a smaller Enterprise's default. As a result, a probability of default that might be acceptable for a smaller Enterprise could be unacceptably high for a larger Enterprise, necessitating the need for an Enterprise-specific stability capital buffer based on size. For similar reasons, a smaller leverage buffer may not be appropriate for a larger institution, and a larger leverage buffer may not be appropriate for a smaller institution. Therefore, a leverage buffer that adjusts with the stability capital buffer would help resolve this type of inconsistency and allow the leverage capital framework to better serve as a credible backstop to the risk-based capital framework.

Fourth, a dynamic PLBA that is tied to the stability capital buffer would further align the ERCF with Basel III standards. Internationally, GSIBs are required to hold a leverage buffer equal to 50 percent of their higher loss-absorbency risk-based requirements—a measure akin to the GSIB surcharge in the U.S. banking framework. FHFA believes that tailoring an Enterprise's leverage ratio to its business activities and risk profile, to the extent that these characteristics are related to an Enterprise's share of the residential mortgage market, will allow for leverage to remain a credible backstop to risk-based capital without discouraging the Enterprise from participating in low-risk activities.

Question 2: Is the proposed PLBA appropriately formulated? What adjustments, if any, would you recommend?

Question 3: Is the PLBA necessary for the ERCF's leverage framework to be considered a credible backstop to the risk-based capital requirements and PCCBA?

Question 4: In light of the proposed changes to the PLBA and the CRT securitization framework, is the prudential risk weight floor of 20 percent on single-family and multifamily mortgage exposures appropriately calibrated? What adjustments, if any, would you recommend?

B. CRT

CRT Risk Weight Floor

The proposed rule would replace the prudential floor of 10 percent on the risk weight assigned to any retained CRT exposure with a prudential floor of 5 percent on the risk weight assigned to any retained CRT exposure.

The prudential risk weight floor plays an important role in the ERCF securitization framework. The risk weight floor is designed to mitigate certain risks and limitations associated with underlying historical data and models, including that crisis-era losses at the Enterprises were mitigated by federal government support that may not be repeated during the next crisis and that potential material risks are not assigned a risk-based capital requirement. In addition, banking agencies believe requiring more capital on a transaction-wide basis than would be required if the underlying assets had not been securitized is important in reducing the likelihood of regulatory capital arbitrage through securitizations.¹⁶ CRT may pose similar structural risks that merit a departure from capital neutrality. Therefore, the ERCF's risk weight floor helps mitigate the model risk associated with the calibration of the credit risk capital requirements of the underlying exposures and the model risk posed by the calibration of the adjustments for loss-timing and counterparty risks.

In sizing the 10 percent prudential risk weight floor, FHFA sought to promote consistency with the U.S. banking framework and strike an appropriate balance between permitting CRT while also mitigating the safety and soundness, mission, and housing stability risk that might be posed by some CRT. FHFA continues to believe

that an Enterprise retains credit risk to the extent it retains CRT exposures and that such risk should be appropriately capitalized. There is the risk that the structuring of some CRT is driven by regulatory arbitrage, with an Enterprise focused on CRT structures that obtain capital relief that is disproportionate to the modeled credit risk actually transferred. There is also the risk that a CRT will not perform as expected in transferring credit risk to third parties, perhaps because a court will not enforce the contractual terms of the CRT structure as expected. Because CRT tranches, even senior CRT tranches, are not risk-free, each Enterprise should maintain regulatory capital to absorb losses on those retained CRT exposures. However, FHFA believes that the current CRT risk weight floor may not achieve the proper balance between permitting CRT and safety and soundness.

As currently calibrated, the 10 percent floor on the risk weight assigned to a retained CRT exposure unduly decreases the capital relief provided by CRT and reduces an Enterprise's incentives to engage in CRT. This occurs in part because the aggregate credit risk capital required for a retained CRT exposure is often greater than the aggregate credit risk capital required for the underlying exposures, especially when the credit risk capital requirements on the underlying whole loans and guarantees are low or the CRT is seasoned. Decreasing the CRT risk weight floor to 5 percent would directly lessen this disincentive while still ensuring that all retained exposures are treated as being not risk-free.

In addition, the 10 percent risk weight floor discourages CRT through its duplicative nature. Per the ERCF's operational criteria for CRT, FHFA must approve each transaction as being effective in transferring the credit risk of one or more mortgage exposures to another party, taking into account any counterparty, recourse, or other risk to the Enterprise and any capital, liquidity, or other requirements applicable to counterparties.¹⁷ This regulatory approval process mitigates the safety and soundness risk posed by CRT structures and contractual terms, lessening the need for a tranche level risk weight floor as high as 10 percent. Moreover, the Enterprises are able to further lessen the need for a punitive CRT risk weight floor with their ability to mitigate unknown risks through their underwriting standards and servicing and loss mitigation programs. The standards and programs are flexible,

¹⁶ See *Regulatory Capital Rules: Regulatory Capital, Implementation of Basel III, Capital Adequacy, Transition Provisions, Prompt Corrective Action, Standardized Approach for Risk-weighted Assets, Market Discipline and Disclosure Requirements, Advanced Approaches Risk-Based Capital Rule, and Market Risk Capital Rule*, 78 FR 62018, 62119 (Oct. 11, 2013).

¹⁷ 12 CFR 1240.41(c)(2).

rigorous, and constantly evolving, helping minimize losses through the entire life cycle of a mortgage loan.

FHFA continues to believe that CRT can play an important role in ensuring that each Enterprise operates in a safe and sound manner and is positioned to fulfill its statutory mission across the economic cycle. FHFA also continues to believe that an Enterprise does retain some credit risk on its CRT and that the risk should be appropriately capitalized. FHFA believes that a 5 percent CRT risk weight floor will enhance the safety and soundness of the Enterprises by increasing the incentives to undertake risk transfer activities while continuing to capitalize retained CRT tranches against structure, model, unforeseen, and other risks. Furthermore, lowering the tranche level risk weight floor should reduce the extent to which the CRT effectiveness adjustments may require more regulatory capital for retained CRT exposures than is necessary to ensure safety and soundness, and help ensure that FHFA does not unduly discourage CRT on mortgage exposures with risk profiles similar to those of recent acquisitions by the Enterprises.

Question 5: Is the 5 percent prudential floor on the risk weight for a retained CRT exposure appropriately calibrated? What adjustment, if any, would you recommend?

Overall Effectiveness Adjustment

The proposed rule would remove the requirement that an Enterprise must apply an overall effectiveness adjustment to its retained CRT exposures in accordance with the ERCF's securitization framework in 12 CFR 1240.44(f) and (i).

FHFA included an overall effectiveness adjustment in the CRT securitization framework largely in response to comments received on FHFA's 2018 notice of proposed rulemaking on Enterprise capital. Commenters argued that CRT has less loss-absorbing capacity than an equivalent amount of equity financing due to the upfront and ongoing costs of CRT, and that while CRT coverage is only on a specified pool, equity financing can cross-cover risks throughout the balance sheet.

However, commenters on the 2020 ERCF notice of proposed rulemaking argued that while these considerations are reasonable, in the context of the totality of the proposed CRT framework and a credible leverage ratio requirement as a backstop, the overall effectiveness adjustment is not needed and creates unnecessary disincentives for the Enterprises to engage in CRT. In

addition, commenters stated that the CRT tranche risk weight floor covers the risk that a CRT will not perform as expected in transferring credit risk to third parties, which is similar to the risk that the overall effectiveness adjustment was designed to cover.

Unlike the counterparty and loss-timing effectiveness adjustments in the CRT securitization framework, the overall effectiveness adjustment does not target specific risks. For this reason, and given the opinions of commenters on the overall effectiveness adjustment, FHFA has determined that it is an appropriate place to make a refinement within the CRT securitization framework to further promote the use of CRT without increasing safety and soundness risks at the Enterprises. FHFA is proposing to remove the adjustment rather than to reduce it due to the lack of empirical evidence suggesting that a lower overall effectiveness adjustment is less duplicative than the adjustment in the ERCF final rule published on December 17, 2020.

Question 6: Is the removal of the overall effectiveness adjustment within the CRT securitization framework appropriate in light of the proposed rule's 5 percent prudential floor on the risk weight for retained CRT exposures?

Adjustments to CRT Capital Relief

The two proposed CRT modifications would increase the capital relief afforded an Enterprise for well-structured CRT on many common mortgage exposures, increasing incentives for the Enterprises to engage in CRT. For existing CRT, the two changes would increase capital relief compared to the current ERCF; however, the changes may not impact future CRT in exactly the same way. Each Enterprise has designed its existing CRT structures with attachment and detachment points, collateralization, and other terms based on the current ERCF and previous guidance. Each Enterprise will likely be able to structure the tranches and other aspects of its future CRT somewhat differently, taking into account modifications in any finalized rule amendments. Nonetheless, FHFA believes that the proposed rule's modifications would reduce the extent to which the CRT methodology may require more regulatory capital for retained CRT exposures than is necessary to ensure safety and soundness. FHFA also believes that these modifications would provide each Enterprise a mechanism for flexible and substantial capital relief through CRT, and CRT likely will remain a valuable tool for managing

credit risk and that each Enterprise will base its CRT decisions on its own risk management assessments, not solely on the regulatory risk-based capital requirements.

The proposed rule would implement a modified ERCF CRT framework through which an Enterprise determines its credit risk-weighted assets for any eligible retained CRT exposures and any other credit risk that might be retained on its CRT. Under the proposed rule, an Enterprise would calculate credit risk-weighted assets for retained credit risk in a CRT using risk weights and exposure amounts for each CRT tranche. The exposure amounts of the retained CRT exposures for each tranche would be increased by adjustments to reflect counterparty credit risk and the length of CRT coverage (*i.e.*, remaining time until maturity). Unlike the current ERCF, the proposed framework would not include an overall effectiveness adjustment. Further, the proposed rule would also set a credit risk capital requirement floor for retained risk through a tranche-level risk weight floor of 5 percent rather than 10 percent.

The two proposed modifications to the CRT securitization framework could lead to a significant increase in capital relief. For Fannie Mae and Freddie Mac combined, capital relief from single-family CRT would increase by an estimated 45 percent, while capital relief from multifamily CRT would increase by an estimated 33 percent. Together, aggregate capital relief on the Enterprises' books of business would increase by an estimated 40 percent, where the increase is driven primarily by the change to the CRT tranche risk weight floor as evidenced by the example below. These modifications could help to ensure that the rule does not create undue disincentives to utilize CRTs.

Question 7: Is the proposed approach to determining the credit risk capital requirement for retained CRT exposures appropriately formulated? What adjustments, if any, would you recommend?

Question 8: Will the proposed amendments to the CRT securitization framework provide the Enterprises with sufficient incentives to engage in more CRT transactions without compromising safety and soundness?

CRT Example

To provide clarity on how the proposed modifications would alter the CRT risk weight calculations, we provide an example using the same stylized CRT that was used as an example in the ERCF notice of proposed

rulemaking. Consider the following inputs from an illustrative CRT:

- \$1,000 million in unpaid principal balance of performing 30-year fixed rate single-family mortgage exposures with original loan-to-values (OLTVs) greater than 60 percent and less than or equal to 80 percent;
- CRT coverage term of 10 years;
- Three tranches—B, M1, and AH—where tranche B attaches at 0% and

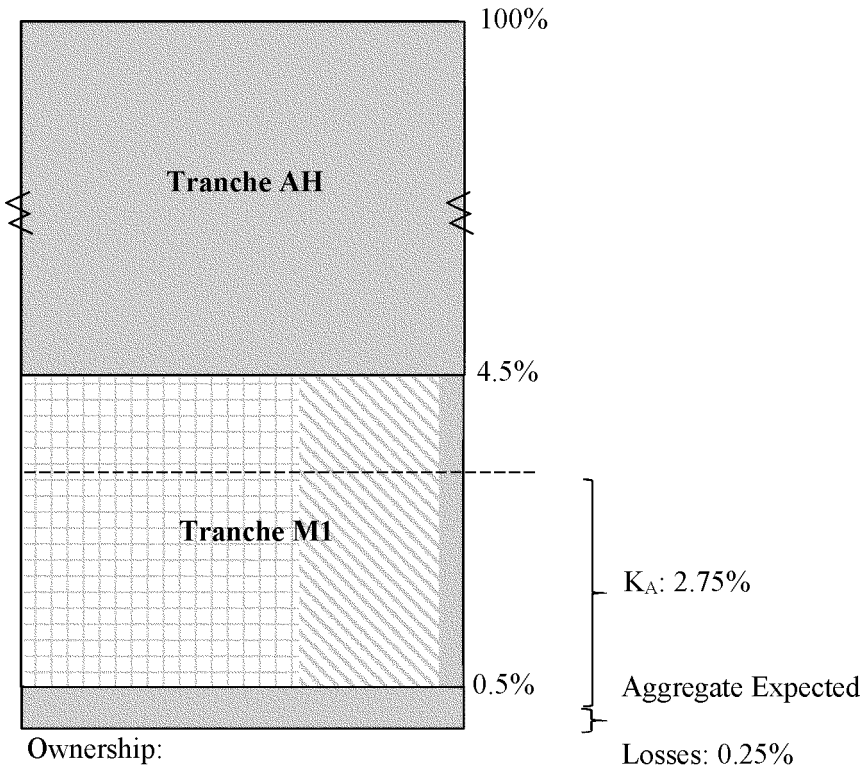
detaches at 0.5%, tranche M1 attaches at 0.5% and detaches at 4.5%, and tranche AH attaches at 4.5% and detaches at 100%;

- Tranches B and AH are retained by the Enterprise, and ownership of tranche M1 is split between capital markets (60 percent), a reinsurer (35 percent), and the Enterprise (5 percent);
- The aggregate credit risk-weighted assets on the single-family mortgage

exposures underlying the CRT are \$343.8 million;

- Aggregate expected losses on the single-family mortgage exposures underlying the CRT of \$2.5 million; and
- The reinsurer posts \$2.8 million in collateral, has a counterparty financial strength rating of 3, and does not have a high level of mortgage concentration risk.

Figure 3: Single-family CRT Example



Tranche AH: 100% retained (in solid gray).

Tranche M1: 60% to capital markets (gray grid lines), 35% reinsured (in gray diagonal lines), and 5% retained (in solid gray).

Tranche B: 100% retained (in solid gray).

The Enterprises would first calculate risk weights for each tranche assuming full effectiveness of the CRT in transferring credit risk on the underlying mortgage exposures. In general, tranche risk weights are the highest for the riskiest, most junior tranches (such as tranche B), and lower for the more senior tranches (such as tranches M1 and AH). The proposed rule would lower risk weights on senior tranches compared to the current ERCF.

For the illustrative CRT, the overall risk weights for the proposed rule across tranches AH, M1, and B are 5%, 783%, and 1,250%, where 5% reflects the proposed minimum risk weight. By comparison, the overall risk weights under the ERCF across tranches AH, M1, and B are 10%, 785%, and 1,250%, where 10% reflects the minimum risk weight. The difference between the M1 risk weights, 783% for the proposed rule and 785% for the ERCF, reflects a

weighted average risk weight calculation for M1 because M1’s attachment and detachment points straddle stress loss. That is, the weighted-average risk weight would be the average of 1,250 percent, weighted by the portion of the tranche exposed to projected stress loss, and the minimum risk weight (5 percent for the proposed rule and 10 percent for ERCF) weighted by the portion of the tranche not exposed to projected stress loss.

Risk weights from the proposed rule:

$$\begin{aligned}
 RW_{\%,AH} &= 5\% \text{ because } K_A + AggEL_{\%} \leq 4.5\% \\
 RW_{\%,M1} &= 1250\% * \frac{K_A + AggEL_{\%} - 0.5\%}{4.5\% - 0.5\%} + 5\% * \frac{4.5\% - (K_A + AggEL_{\%})}{4.5\% - 0.5\%} \\
 &= 783\% \text{ because } 0.5\% < K_A + AggEL_{\%} < 4.5\% \\
 RW_{\%,B} &= 1250\% \text{ because } K_A + AggEL_{\%} \geq 0.5\%
 \end{aligned}$$

Risk weights from the ERCF:

$$\begin{aligned}
 ERCF\_RW_{\%,AH} &= 10\% \text{ because } K_A + AggEL_{\%} \leq 4.5\% \\
 ERCF\_RW_{\%,M1} &= 1250\% * \frac{K_A + AggEL_{\%} - 0.5\%}{4.5\% - 0.5\%} + 10\% * \frac{4.5\% - (K_A + AggEL_{\%})}{4.5\% - 0.5\%} \\
 &= 785\% \text{ because } 0.5\% < K_A + AggEL_{\%} < 4.5\% \\
 ERCF\_RW_{\%,B} &= 1250\% \text{ because } K_A + AggEL_{\%} \geq 0.5\%
 \end{aligned}$$

where

$$\begin{aligned}
 K_A &= 100\% * \frac{RWA_{\$} * 8\%}{AggUPB_{\$}} = 100\% * \frac{\$343.8m * 8\%}{\$1000m} = 2.75\% \\
 AggEL_{\%} &= 100\% * \frac{EL\$}{AggUPB_{\$}} = 100\% * \frac{\$2.5m}{\$1000m} = 0.25\%.
 \end{aligned}$$

Next, the Enterprise would calculate the adjusted exposure amount of its retained CRT exposures to reflect the effectiveness of the CRT in transferring credit risk on the underlying mortgage exposures. For the illustrative CRT, tranches AH and B are retained by the Enterprise, and do not need further adjustment. Risk associated with tranche M1 is transferred through a capital markets transaction and a loss sharing agreement. For the proposed rule, risk transfer on this tranche is subject to the following two effectiveness adjustments, which are reflected in the Enterprise's adjusted exposure amount: Loss sharing effectiveness adjustment (LSEA) and

loss timing effectiveness adjustment (LTEA). The current ERCF includes an additional on-the-top overall effectiveness adjustment (OEA), which acts like a capital relief haircut.

Both the proposed rule and the current ERCF utilize the same methodology when accounting for the effectiveness of loss sharing on tranche M1. In particular, both methods adjust the Enterprise's exposure amount on tranche M1 to reflect the retention of some of the counterparty credit risk that was nominally transferred to the counterparty. To do so, the methods adjust effectiveness for: (i) Uncollateralized unexpected loss (UnCollatUL); and (ii) uncollateralized

risk-in-force above stress loss (SRIF). The approaches differ in their capitalization of SRIF. The proposed rule would capitalize SRIF at a 5% risk weight and the current ERCF capitalizes SRIF at a 10% risk weight, where the difference reflects the different risk weight floors.

For the illustrative CRT, the counterparty haircut is 5.2% as per the ERCF's single-family CP haircuts, UnCollatUL is 42.5%, and SRIF is 37.5%. The proposed rule's LTEA on tranche M1 would be 96.5%, which when rounded, is the same figure for LTEA under the current ERCF.

LSEA from the proposed rule:

$$LSEA_{\%,M1} = \left(1 - 5.2\% * \frac{(UnCollatUL_{\%,M1} * 1250\% + SRIF_{\%,M1} * 5\%)}{RW_{\%,M1}} \right) = 96.5\%$$

LSEA from the current ERCF:

$$ERCF\_LSEA_{\%,M1} = \left(1 - 5.2\% * \frac{(UnCollatUL_{\%,M1} * 1250\% + SRIF_{\%,M1} * 10\%)}{ERCF\_RW_{\%,M1}} \right) = 96.5\%$$

where

$$UnCollatUL_{\%,M1} = 100\% * \left(\frac{K_A + AggEL_{\%} - A}{D - A} \right) - Collat_{\%,RIF,M1}$$

$$UnCollatUL_{\%,M1}$$

$$= 100\% * \left(\frac{3\% - 0.5\%}{4.5\% - 0.5\%} \right) - 100\% * \frac{\$2.8m}{\$1,000 * (4.5\% - 0.5\%) * 35\%} = 42.5\%$$

$$SRIF_{\%,M1} = 100\% - 100\% * \max \left(\left(\frac{3\% - 0.5\%}{4.5\% - 0.5\%} \right), \frac{\$2.8m}{\$1,000 * (4.5\% - 0.5\%) * 35\%} \right) = 37.5\%$$

Both the proposed rule and the current ERCF utilize the same methodology when accounting for effectiveness from the timing of coverage by adjusting the Enterprise's exposure amount for tranche M1 to reflect the retention of some loss timing risk that was nominally transferred. The loss timing factor addresses the

mismatch between lifetime losses on the 30-year fixed-rate single-family mortgage exposures underlying the CRT and the CRT's coverage. The loss timing factor for the illustrative CRT with 10 years of coverage and backed by 30-year fixed-rate single-family whole loans and guarantees with OLTVs greater than 60 percent and less than or equal to 80

percent is 88 percent for both the capital markets transaction and the loss sharing agreement. For the illustrative CRT, tranche M1's LTEA is 85.6% and is derived by scaling stress loss by the 88% loss timing factor.

LTEA from the proposed rule and the current ERCF:

$$LTEA_{\%,M1} = ERCF\_LTEA_{\%,M1} = 100\% * \frac{LTK_{A,LS} + AggEL_{\%} - A}{K_A + AggEL_{\%} - A} = 100\% * \frac{2.39\% + 0.25\% - 0.5\%}{2.75\% + 0.25\% - 0.5\%} = 85.6\%$$

Where

$$LTK_{A,\%} = \max ((2.75\% + 0.25\%) * 88\% - 0.25\%, 0\%) = 2.39\%$$

The current ERCF includes a third adjustment, the OEA, that the proposed rule omits.

OEA from the current ERCF:

$$ERCF\_OEA_{\%} = 100\% * (1.06667 - 4.1667 * K_A) = 95.2\%$$

The next steps convert the effectiveness adjustments into Enterprise exposures. In particular, the adjusted exposure amounts (AEAs) combine the effectiveness adjustments, aggregate UPB, tranche thickness, and

an adjustment for expected losses (to tranche B in the example). For the illustrative CRT, the proposed rule would calculate AEAs as follows:

$$AEA_{\%,AH} = EAE_{\%,AH} * AggUPB_{\$} * (D - A) = \$1,000m * (100\% - 4.5\%) = \$955m$$

$$\begin{aligned}
 AEA_{\%,M1} &= EAE_{\%,M1} * AggUPB_{\$} * (D - A) \\
 &= 19.7\% * \$1,000m * (45\% - 0.5\%) \\
 &= \$7.9m
 \end{aligned}$$

$$AE A_{\%,B} = EAE_{\%,B} * AggUPB_{\$} * (D - A) * \left(1 - \frac{AggEL_{\%} - A}{D - A}\right)$$

$$= \$1,000m * (0.5\% - 0\%) * 50\% = \$2.5m$$

where the Enterprise's adjusted exposures (EAEs) for tranches A and B are 100% and

$$EAE_{\%,M1} = 100\% - (60\% * 85.6\%) - (35\% * 96.5\% * 85.6\%) = 19.7\%.$$

The current ERCF calculates AEAs including the OEA, thus increasing the Enterprise's exposure on M1. For tranches AH and B, the current ERCF's AEAs are the same as those of the proposed rule because the Enterprise does not transfer risk on the AH and B tranches.

$$\begin{aligned}
 ERCF\_AEA_{\%,M1} &= ERCF\_EAE_{\%,M1} * \\
 &AggUPB_{\$} * (D - A) = 23.6\% * \\
 &\$1,000m * (4.5\% - 0.5\%) = \$9.4m \\
 ERCF\_EAE_{\%,M1} &= 100\% - (60\% * \\
 &85.6\% * 95.2\%) - (35\% * 96.5\% * \\
 &85.6\% * 95.2\%) = 23.6\%
 \end{aligned}$$

Finally, the risk weights and exposures are combined to calculate risk-weighted assets. For the illustrative CRT, the proposed rule would calculate risk-weighted assets (RWA) as follows:

$$\begin{aligned}
 RWA_{\$,AH} &= AEA_{\$,AH} * RW_{\%,AH} = \$955m \\
 &* 5\% = \$47.8m \\
 RWA &= AEA_{\$,M1} * RW_{\%,M1} = \$7.9m * \\
 &783\% = \$61.8m \\
 RWA &= AEA_{\$,B} * RW_{\%,B} = \$2.5m * \\
 &1250\% = \$31.3m
 \end{aligned}$$

with total RWAs on the retained CRT exposures at \$140.8 million, a decline of \$202.9 million from the aggregate credit risk-weighted assets on the underlying single-family mortgage exposures of \$343.8 million.

By comparison, the current ERCF's total RWA are higher primarily due to its higher risk weight floor on the senior AH exposure:

$$\begin{aligned}
 ERCF\_RWA_{\$,AH} &= ERCF\_AEA_{\$,AH} * \\
 &ERCF\_RW_{\%,AH} = \$955m * 10\% = \\
 &\$95.5m \\
 ERCF\_RWA_{\$,M1} &= ERCF\_AEA_{\$,M1} * \\
 &ERCF\_RW_{\%,M1} = \$9.4m * 785\% = \\
 &\$74.1m \\
 ERCF\_RWA_{\$,B} &= ERCF\_AEA_{\$,B} * \\
 &ERCF\_RW_{\%,B} = \$2.5m * 1250\% = \\
 &\$31.3m
 \end{aligned}$$

with total RWAs on the retained CRT exposures at \$200.8 million.

Overall, for this stylized CRT, the proposed rule's total RWA capital relief of \$202.9 million is 42 percent higher than the \$143.0 million in capital relief from the current ERCF.

C. ERCF Technical Corrections

The proposed rule would make technical corrections to the ERCF related to definitions, variable names, the single-family countercyclical adjustment, and CRT formulas that were not accurately reflected in the ERCF final rule published on December 17, 2020. These technical corrections would revise the ERCF for the following items:

- In § 1240.2, the definition of "Multifamily mortgage exposure" would be moved from its current location to a location that follows alphabetical order relative to the other definitions within the section. The definition of a multifamily mortgage exposure would not change.
- In § 1240.33, the definition of "Long-term HPI trend" would be updated to correct a typographical error that resulted in only the coefficient of the trendline formula, 0.66112295, being published. The corrected trendline formula would be $0.66112295e^{0.002619948*t}$. The Enterprises use the long-term HPI trend as the basis for calculating the single-family countercyclical adjustment. As published, the trendline would be a time-invariant horizontal line rather than a time-varying exponential function.

- In § 1240.33, the definition of OLTV for single-family mortgage exposures would be amended to include the parenthetical (*original loan-to-value*) after the acronym to provide additional clarity as to the meaning of OLTV. Single-family OLTV would continue to be based on the lesser of the appraised value and the sale price of the property securing the single-family mortgage.

- In § 1240.37, the second paragraph (d)(3)(iii) would be redesignated as paragraph (d)(3)(iv) to correct a typographical error.

- In § 1240.43(b)(1), the term "KG" would be replaced with " K_G " to correct a typographical error.

- In § 1240.44,

- In paragraph (b)(9)(i)(C), the term " $(LTFUPB\%)$ " would be replaced with the term " $(LTFUPB_{\%})$ " to correct a typographical error;

- In paragraph (b)(9)(i)(D), the term " $LTF\%$ " would be replaced with the term " $LTF_{\%}$ " to correct a typographical error;

- In paragraph (b)(9)(ii), the term " $LTF\%$ " would be replaced with the term " $LTF_{\%}$ " to correct a typographical error;

- In paragraph (b)(9)(ii)(B), the term " $(CRTF15\%)$ " would be replaced with the term " $(CRTF15_{\%})$ " to correct a typographical error;

- In paragraph (b)(9)(ii)(C), the term " $(CRT80NotF15\%)$ " would be replaced with the term " $(CRT80NotF15_{\%})$ " to correct a typographical error.

- In paragraph (b)(9)(ii)(E)(2)(i), the equation would be revised to correct a typographical error. The revised equation would be:

$$\begin{aligned}
 LTF_{\%} &= (CRTLT15 * CRTF15_{\%}) + \\
 &(CRTLT80Not15 * CRT80NotF15_{\%}) \\
 &+ (CRTLTGT80Not15 * \\
 &(1 - CRT80NotF15_{\%} - CRTF15_{\%}));
 \end{aligned}$$

- In paragraph (b)(9)(ii)(E)(2)(iii), the term " $LTF\%$ " would be replaced with the term " $LTF_{\%}$," to correct a typographical error;

- In paragraph (c) introductory text, the term " $RW\%$ " would be replaced with the term " $RW_{\%}$ " to correct a typographical error;

- In paragraph (c)(1), the term " $AggEL\%$ " would be replaced with the term " $AggEL_{\%}$ " to correct a typographical error;

- In paragraph (g), the first three equations would be combined into one equation to correct a typographical error that erroneously split the equation into three distinct parts. The revised equation would be:

if $(SLS_{\%,Tranche} - ELS_{\%,Tranche}) > 0$ then

$$LTEA_{\%,Tranche,CM} = \frac{100\% * \max\left(0, \min\left(1, \frac{LTK_{A,CM} + AggEL_{\%} - A}{D - A}\right)\right) - ELS_{\%,Tranche}}{(SLS_{\%,Tranche} - ELS_{\%,Tranche})}$$

$$LTEA_{\%,Tranche,LS} = \frac{100\% * \max\left(0, \min\left(1, \frac{LTK_{A,LS} + AggEL_{\%} - A}{D - A}\right)\right) - ELS_{\%,Tranche}}{(SLS_{\%,Tranche} - ELS_{\%,Tranche})}$$

IV. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) requires that regulations involving the collection of information receive clearance from the Office of Management and Budget (OMB). The proposed rule contains no such collection of information requiring OMB approval under the PRA. Therefore, no information has been submitted to OMB for review.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that a regulation that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an initial regulatory flexibility analysis describing the regulation's impact on small entities. FHFA need not undertake such an analysis if the agency has certified that the regulation will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). FHFA has considered the impact of the proposed rule under the Regulatory Flexibility Act. The of FHFA certifies that the proposed rule, if adopted as a final rule, would not have a significant economic impact on a substantial number of small entities because the proposed rule is applicable only to the Enterprises, which are not small entities for purposes of the Regulatory Flexibility Act.

Proposed Rule

List of Subjects for 12 CFR Part 1240

Capital, Credit, Enterprise, Investments, Reporting and recordkeeping requirements.

Authority and Issuance

For the reasons stated in the Preamble, under the authority of 12 U.S.C. 4511, 4513, 4513b, 4514, 4515–17, 4526, 4611–4612, 4631–36, FHFA proposes to amend part 1240 of title 12 of the Code of Federal Regulation as follows:

Chapter XII—Federal Housing Finance Agency

Subchapter C—Enterprises

PART 1240—CAPITAL ADEQUACY OF ENTERPRISES

■ 1. The authority citation for part 1240 is revised to read as follows:

Authority: 12 U.S.C. 4511, 4513, 4513b, 4514, 4515, 4517, 4526, 4611–4612, 4631–36.

■ 2. Amend § 1240.2 by removing the definition of “Multifamily mortgage exposure” and adding the definition of “Multifamily mortgage exposure” in alphabetical order to read as follows:

§ 1240.2 Definitions.

* * * * *

Multifamily mortgage exposure means an exposure that is secured by a first or subsequent lien on a property with five or more residential units.

* * * * *

■ 3. Amend § 1240.11 by revising paragraph (a)(6) to read as follows:

§ 1240.11 Capital conservation buffer and leverage buffer.

(a) * * *

(6) *Prescribed leverage buffer amount.*

An Enterprise's prescribed leverage buffer amount is 50 percent of the Enterprise's stability capital buffer calculated in accordance with subpart G of this part.

■ 4. Amend § 1240.33(a) by:

■ a. In the definition of “Long-term HPI trend”, removing “0.66112295” and adding “0.66112295e^{0.002619948*t}” in its place; and

■ b. Revising the definition of “OLTV”.
The revision reads as follows:

§ 1240.33 Single-family mortgage exposures.

(a) * * *

OLTV (original loan-to-value) means, with respect to a single-family mortgage exposure, the amount equal to:

- (i) The unpaid principal balance of the single-family mortgage exposure at origination; divided by
- (ii) The lesser of:

(A) The appraised value of the property securing the single-family mortgage exposure; and

(B) The sale price of the property securing the single-family mortgage exposure.

* * * * *

§ 1240.37 [Amended]

■ 5. Amend § 1240.37 by redesignating the second paragraph (d)(3)(iii) as paragraph (d)(3)(iv).

§ 1240.43 [Amended]

■ 6. Amend § 1240.43 in paragraph (b)(1) by removing the term “KG” and adding the term “K_G” in its place.

■ 7. Amend § 1240.44 by:

■ a. In paragraph (b)(9)(i)(C), removing the term “(LTFUPBE%)” and adding the term “(LTFUPB%)” in its place;

■ b. In paragraph (b)(9)(i)(D) introductory text, removing the term “LTF%” and adding the term “LTF%” in its place;

■ c. In paragraph (b)(9)(ii) introductory text, removing the term “LTF%” and adding the term “LTF%” in its place;

■ d. In paragraph (b)(9)(ii)(B), removing the term “(CRTF15%)” and adding the term “(CRTF15%)” in its place;

■ e. In paragraph (b)(9)(ii)(C), removing the term “(CRT80NotF15%)” and adding the term “(CRT80NotF15%)” in its place;

■ f. Revising the equation in paragraph (b)(9)(ii)(E)(2)(i);

■ g. In paragraph (b)(9)(ii)(E)(2)(iii) introductory text, removing the term “LTF%” and adding the term “LTF%,” in its place;

■ h. In paragraph (c) introductory text:

■ i. Removing the term “RW%” and adding the term “RW%” in its place; and

■ ii. Removing “10 percent” and adding the term “5 percent” in its place;

■ i. In paragraph (c)(1), removing the term “AggEL%” and adding the term “AggEL%” in its place;

■ j. In paragraphs (c)(2) and (c)(3)(ii), removing the term “10 percent” and adding the term “5 percent” in its place;

■ k. Revising the first equation in paragraph (d);

- l. In paragraph (e), removing the term “10 percent” and adding the term “5 percent” in its place;
 ■ m. Revising paragraph (f)(2)(i);
 ■ n. In paragraph (g), revising the first three equations;
 ■ o. Revising the first equation in paragraph (h); and

- p. Removing and reserving paragraph (i).
 The revisions read as follows:
§ 1240.44 Credit risk transfer approach (CRTA).
 * * * * *
 (b) * * *

- (9) * * *
 (ii) * * *
 (E) * * *
 (2) * * *
 (i) * * *
 * * * * *
 (d) * * *

$RW_{\%,Tranche}$

$$= \begin{cases} 1,250\% \text{ if } K_A + AggEL_{\%} \geq D \\ 5\% \text{ if } K_A + AggEL_{\%} \leq A \\ 1250\% * \left(\frac{K_A + AggEL_{\%} - A}{D - A} \right) + 5\% * \left(\frac{D - (K_A + AggEL_{\%})}{D - A} \right) \text{ if } A < K_A + AggEL_{\%} < D \end{cases}$$

$$AggEL_{\%} = 100\% * \frac{EL_{\$}}{AggUPB_{\$}}$$

* * * * *
 (f) * * *

(2) *Inputs*—(i) *Enterprise adjusted exposure*. The adjusted exposure (EAE) of an Enterprise with respect to a retained CRT exposure is as follows:

$$EAE_{\%,Tranche} = 100\% - (CM_{\%,Tranche} * LTEA_{\%,Tranche,CM}) - (LS_{\%,Tranche} * LSEA_{\%,Tranche} * LTEA_{\%,Tranche,LS})$$

Where the loss timing effectiveness adjustments (LTEA) for a retained CRT exposure are determined under

paragraph (g) of this section, and the loss sharing effectiveness adjustment (LSEA) for a retained CRT exposure is determined under paragraph (h) of this section.

* * * * *
 (g) * * *

if $(SLS_{\%,Tranche} - ELS_{\%,Tranche}) > 0$ *then*

$LTEA_{\%,Tranche,CM}$

$$= \frac{100\% * \max \left(0, \min \left(1, \frac{LTK_{A,CM} + AggEL_{\%} - A}{D - A} \right) \right) - ELS_{\%,Tranche}}{(SLS_{\%,Tranche} - ELS_{\%,Tranche})}$$

$LTEA_{\%,Tranche,LS}$

$$= \frac{100\% * \max \left(0, \min \left(1, \frac{LTK_{A,LS} + AggEL_{\%} - A}{D - A} \right) \right) - ELS_{\%,Tranche}}{(SLS_{\%,Tranche} - ELS_{\%,Tranche})}$$

* * * * *

(h) * * *

if $(RW_{\%,Tranche} - ELS_{\%,Tranche} * 1250\%) > 0$ *then*

$$LSEA_{\%,Tranche} = \max \left(\left(1 - HC * \frac{(UnCollatUL_{\%,Tranche} * 1250\% + SRIF_{\%,Tranche} * 5\%)}{(RW_{\%,Tranche} - ELS_{\%,Tranche} * 1250\%)} \right), 0\% \right)$$

* * * * *

Sandra L. Thompson,*Acting Director, Federal Housing Finance Agency.*

[FR Doc. 2021–20297 Filed 9–24–21; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39****[Docket No. FAA–2021–0832; Project Identifier MCAI–2020–01550–T]****RIN 2120–AA64****Airworthiness Directives; Bombardier, Inc., Airplanes****AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. This proposed AD was prompted by reports of internal corrosion on the inboard flaps found prior to regularly scheduled maintenance checks. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate a certain aircraft maintenance manual (AMM) task. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by November 12, 2021.

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

For service information identified in this NPRM, contact Bombardier, Inc., Bombardier, Inc., 200 Côte-Vertu Road West, Dorval, Québec H4S 2A3, Canada; telephone 514–855–2999; email ac.yul@aero.bombardier.com; internet <https://www.bombardier.com>. You may view

this service information at the FAA, Airworthiness Products Section, Operational Safety 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 at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0832; 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, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Antariksh Shetty, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email 9-avs-nyaco-cos@faa.gov.

SUPPLEMENTARY INFORMATION:**Comments Invited**

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA–2021–0832; Project Identifier MCAI–2020–01550–T” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to <https://www.regulations.gov>, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial

information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Antariksh Shetty, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email 9-avs-nyaco-cos@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued TCCA AD CF–2020–49R1, dated May 20, 2021 (TCCA AD CF–2020–49R1) (also referred to after this as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. You may examine the MCAI in the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0832.

This proposed AD was prompted by reports of internal corrosion on the inboard flaps found prior to regularly scheduled maintenance checks. The FAA is proposing this AD to address such corrosion, which could result in reduced structural integrity, detachment of the flap, and consequent reduced controllability of the airplane.

See the MCAI for additional background information.

Related Service Information Under 14 CFR Part 51

Bombardier issued the following service information.

- Task 57–51–00–290–801, “Special Detailed Inspection of the Inboard-Flap Internal Ribs,” of Bombardier Global Express Aircraft Maintenance Manual—Part Two—Publication No. BD–700 AMM, Revision 90, dated May 19, 2021.
- Task 57–51–00–290–801, “Special Detailed Inspection of the Inboard-Flap Internal Ribs,” of Bombardier Global Express XRS Aircraft Maintenance Manual—Part Two—Publication No. BD–700 XRS AMM, Revision 68, dated May 19, 2021.

- Task 57–51–00–290–801, “Special Detailed Inspection of the Inboard-Flap Internal Ribs,” of Bombardier Global 6000 Aircraft Maintenance Manual—Part Two—Publication No. GL 6000 AMM, Revision 39, dated May 19, 2021.

- Task 57–51–00–290–801, “Special Detailed Inspection of the Inboard-Flap Internal Ribs,” of Bombardier Global 6500 Aircraft Maintenance Manual—Part Two—Publication No. GL 6500 AMM, Revision 8, dated May 19, 2021.

- Task 57–51–00–290–801, “Special Detailed Inspection of the Inboard-Flap Internal Ribs,” of Bombardier Global 5000 Aircraft Maintenance Manual—Part Two—Publication No. BD–700 AMM, Revision 71, dated May 19, 2021.

- Task 57–51–00–290–801, “Special Detailed Inspection of the Inboard-Flap Internal Ribs,” of Bombardier Global 5000 Featuring Global Vision Flight Deck Aircraft Maintenance Manual—Part Two—Publication No. GL 5000 GVFD AMM, Revision 38, dated May 19, 2021.

- Task 57–51–00–290–801, “Special Detailed Inspection of the Inboard-Flap Internal Ribs,” of Bombardier Global 5500 Aircraft Maintenance Manual—Part Two—Publication No. GL 5500 AMM, Revision 7, dated May 19, 2021.

These documents describe amendments to the AMM to include inspections of the inboard flap internal ribs for corrosion. These documents are distinct since they apply to different airplane serial numbers.

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

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed Requirements of This NPRM

This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate the information specified in AMM Task 57–51–00–290–801 and the compliance times for AMM Task 57–51–00–290–801.

The AMM task corresponds to Part 3, Task 57–51–00–201, Special Detailed Inspection of the Inboard-Flap Internal Ribs, of the applicable Bombardier Time Limits/Maintenance Checks (TLMC), which is referenced in the MCAI.

Costs of Compliance

The FAA estimates that this proposed AD affects 141 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA has determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the agency estimates the average total cost per operator to be \$7,650 (90 work-hours × \$85 per work-hour).

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.

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

Regulatory Findings

The FAA 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) Would not affect intrastate aviation in Alaska, and

(3) Would 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:

Bombardier, Inc.: Docket No. FAA–2021–0832; Project Identifier MCAI–2020–01550–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by November 12, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes, certificated in any category, serial numbers 9001 through 9879 inclusive, 9998, and 60001 through 60033 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Reason

This AD was prompted by reports of internal corrosion on the inboard flaps found prior to regularly scheduled maintenance checks. The FAA is issuing this AD to address internal corrosion on the inboard flaps, which could result in reduced structural integrity, detachment of the flap, and consequent reduced controllability of the airplane.

(f) Compliance

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

(g) Maintenance or Inspection Program Revision

Within 30 days after the effective date of this AD, revise the existing maintenance or

inspection program, as applicable, to include the information specified in Task 57–51–00–290–801, “Special Detailed Inspection of the Inboard-Flap Internal Ribs,” of the applicable

Bombardier Aircraft Maintenance Manual (AMM) identified in figure 1 to paragraph (g) of this AD and to include the following compliance times for Task 57–51–00–290–

801: Within 60 months after the effective date of this AD (for the initial compliance time), and repeat thereafter at intervals not to exceed 60 months.

Figure 1 to paragraph (g) – Applicable AMMs

Airplane Model	Bombardier AMM
BD-700-1A10	Bombardier Global Express Aircraft Maintenance Manual - Part Two - Publication No. BD-700 AMM, Revision 90, dated May 19, 2021
BD-700-1A10	Bombardier Global Express XRS Aircraft Maintenance Manual - Part Two - Publication No. BD-700 XRS AMM, Revision 68, dated May 19, 2021
BD-700-1A10	Bombardier Global 6000 Aircraft Maintenance Manual – Part Two - Publication No. GL 6000 AMM, Revision 39, dated May 19, 2021
BD-700-1A10	Bombardier Global 6500 Aircraft Maintenance Manual – Part Two - Publication No. GL 6500 AMM, Revision 8, dated May 19, 2021
BD-700-1A11	Bombardier Global 5000 Aircraft Maintenance Manual - Part Two - Publication No. BD-700 AMM, Revision 71, dated May 19, 2021
BD-700-1A11	Bombardier Global 5000 Featuring Global Vision Flight Deck Aircraft Maintenance Manual - Part Two - Publication No. GL 5000 GVFD AMM, Revision 38, dated May 19, 2021
BD-700-1A11	Bombardier Global 5500 Aircraft Maintenance Manual - Part Two - Publication No. GL 5500 AMM, Revision 7, dated May 19, 2021

(h) No Alternative Actions or Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (e.g., inspections) or intervals, may be used unless the actions or intervals, are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) of this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, New York 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 ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.’s TCCA Design Approval Organization (DAO). If approved by

the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) TCCA AD CF–2020–49R1, dated May 20, 2021, for related information. This MCAI may be found in the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0832.

(2) For more information about this AD, contact Antariksh Shetty, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email 9-avs-nyaco-cos@faa.gov.

(3) For service information identified in this AD, contact Bombardier, Inc., 200 Côte-Vertu Road West, Dorval, Québec H4S 2A3, Canada; telephone 514–855–2999; email

ac.yul@aero.bombardier.com; internet <https://www.bombardier.com>. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

Issued on September 21, 2021.

Gaetano A. Sciortino,

*Deputy Director for Strategic Initiatives,
Compliance & Airworthiness Division,
Aircraft Certification Service.*

[FR Doc. 2021-20805 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE

Office of the Secretary

15 CFR Part 15

[Docket No. 210915-0188]

RIN 0605-AA52

Department of Commerce Regulations on Procedures for Responding to Requests for Documents or Testimony for Use in Legal Proceedings

AGENCY: Office of the Secretary, Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: This proposed rule would revise the Department of Commerce's (Commerce) regulations, known as "Touhy regulations," that set forth the procedures for responding to requests for documents or testimony for use in legal proceedings. The Department intends these revisions to provide greater clarity to entities seeking documents or testimony from current or former Department employees. Specifically, these revisions would clarify, update, and streamline the language of several provisions, provide greater transparency regarding the factors that the agency will consider when reviewing such requests, and more directly address issues that frequently arise in requests for documents or testimony based on the facts of the request, such as whether the testimony requested is that of a former employee, whether the United States is a party to the underlying legal proceedings, or whether the testimony or documents are requested from the Office of the Inspector General.

DATES: Written comments must be received on or before October 27, 2021.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 0605-AA52, by either of the following methods:

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

- **Email:** ssharma@doc.gov. Include the RIN 0605-AA52 in the subject line.

Instructions: All submissions received must include the agency name and docket number or RIN for this rulemaking. Electronic comments may be submitted via www.regulations.gov prior to midnight eastern time on October 27, 2021. Comments may not be considered if they are sent by any other method, to any other address or individual, or received after the comment period ends at 11:59 p.m. eastern time on the date of comment period closure. All comments received are a part of the public record and will generally be posted without change to <http://www.regulations.gov>. For posted comments, all personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender is publicly accessible. Anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous) will be accepted. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe portable document format (PDF) only.

Submit written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Sapna Sharma, General Litigation Division, Office of the General Counsel, U.S. Department of Commerce, 1401 Constitution Ave. NW, Rm. 5890, Washington, DC 20230; ssharma@doc.gov.

SUPPLEMENTARY INFORMATION: This rulemaking proposes revisions to the Department's regulations promulgated pursuant to 5 U.S.C. 301. Sections 15 CFR 15.11-15.18 set forth the procedures currently applicable to requests submitted to Commerce for the testimony of employees and the production of documents for use in legal proceedings to which the agency is not a party. These regulations are also known as "Touhy regulations," in reference to the case in which the Supreme Court upheld the validity of such agency regulations promulgated pursuant to 5 U.S.C. 301. *See United*

States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951).

These proposed revisions to the Department's regulations clarify the process by which demands for documents or testimony are to be made and considered. They also update and streamline the language of several provisions where past experiences suggest need for elucidation. Additionally, the Department is revising these regulations to more directly address issues that arise frequently in requests for documents or testimony. The Department intends these revisions to provide greater clarity to entities seeking documents or testimony from current or former Department employees. Following is a description of the revisions to specific provisions of the Touhy regulations.

Section 15.11—Scope.

Paragraph (a) would be revised to more clearly set forth the scope and applicability of this subpart, and to state upfront that an employee's compliance with any demand for information or testimony requires prior authorization by the appropriate legal officers. New paragraph (c) would be added to clarify that this subpart does not apply to proceedings in which the Department is a party. New paragraph (d) would be added to direct requests for documents or testimony from the United States Patent and Trademark Office (USPTO) to the applicable USPTO *Touhy* regulations; all references to the USPTO in the previous regulation would be deleted throughout the revised Subpart B. New paragraph (e) would combine previous paragraph (c) with previous section 15.17 to clarify that the Department will determine if other statutory authorities exist that address disclosure of the requested information before applying the procedures in this subpart.

Section 15.12—Definitions.

Broadly, this section has been revised to provide additional detail in definitions and add definitions for new terms used in the proposed revisions. Paragraph (a) has been revised to provide more detail in the definition of *agency counsel*. Paragraphs (c) and (i) define the Office of the Inspector General and its Counsel, reflecting the proposed addition of new section 15.17 to address requests that are made for documents or testimony from the Office of the Inspector General. Paragraphs (b), (d)–(h), and (j)–(m) have been revised to clarify language and provide greater detail.

Section 15.13—Demand for testimony or production of documents: *Department procedures.*

This proposed rule would significantly revise section 15.13. The rule proposes to move from section 15.13 to section 15.16(a) the policies and considerations that Commerce will use in determining responses to demands for documents or testimony. Paragraph (a) of revised section 15.13 restates the existing rule that no document or information may be produced without authorization from the General Counsel or appropriate agency counsel. Paragraph (b) of revised section 15.13 would set forth in more detail the notification requirements for requests submitted pursuant to this subpart; these notification requirements were formerly found at section 15.14(c). Paragraph (b)(1) would be revised to include the full address for mailed requests and an email address for submitting requests electronically. Paragraph (b)(2) would refer requestors to regulations for the United States Patent and Trademark Office, for requests relating to that agency. Paragraph (c) would direct employees to forward any demand to the appropriate office within the General Counsel's Office; this direction and contact information is currently set forth in section 15.14(a) of the regulations. Paragraph (d) would specifically address the course of action that the Department will take if it determines its employee should not comply with a subpoena. In addition, this paragraph would specify that electronic service of subpoenas is not authorized.

Section 15.14—Demand for testimony or production of documents in matters in which the United States is not a party.

This section would be revised to consolidate the procedures to be followed for requests relating to matters in which the United States is not a party to proceedings, which were previously interspersed in sections 15.14, 15.15, and 15.16 of the current regulations. Notably, paragraph (g)(2) of revised section 15.14 would set forth new rules and procedures for former Department employees who are asked to provide opinion or expert testimony in such proceedings; these rules and procedures had not previously been addressed. The procedures for matters in which the United States is a party would now be provided separately in new section 15.15.

Section 15.15—Demand for testimony or production of documents in matters in which the United States is a party.

This section would be partly new, and would encompass provisions found in current sections 15.16 and 15.18 on expert and opinion testimony. It would set forth the procedures for requests

relating to matters in which the United States, but not the Department, is a named party. Paragraph (a) would address requests received from entities other than the United States, in proceedings in which the United States is a party, and would require that counsel of record representing the interests of the United States or one of its other agencies and instrumentalities be informed of such demands. Paragraph (b) would address requests received from agencies or instrumentalities of the United States other than the Department. Notably, and consistent with past practice, paragraph (b) would now state that the General Counsel may require reimbursement to the Department of expenses associated with a Department employee providing consultations on behalf of the United States. Paragraph (c) would separately set forth the procedures for expert or opinion testimony for both current and former employees in matters in which the United States, but not the Department, is a named party.

Section 15.16—Demand for testimony or production of documents: Department and Policy Considerations.

This proposed rule would revise section 15.16 to set forth in greater detail the factors that, as appropriate, will be considered in deciding whether the requested disclosure of information or testimony is in the interests of the Department. The policy factors in previous section 15.13(a)–(f) would be moved to this section and expanded to better inform non-government requestors. Paragraph (a)(1–9) would set forth a list of factors to be considered. Paragraph (b)(1–3) would set forth additional considerations for the General Counsel to weigh, once requirements in sections 15.14 and 15.15 of this subpart have been satisfied. Finally, new paragraph (c)(1–8) would set forth a non-exclusive list of the factors that preclude disclosure of information that may be requested.

Section 15.17—Subpoenas and demands served upon employees or former employees of the Office of the Inspector General.

The proposed rule would add this new section to address requests that are made for documents or testimony from the Office of the Inspector General and to clarify that this subpart applies to requests for documents or testimony from the Office of the Inspector General. This section would provide the notification procedures for requests to the Inspector General.

Classification

This rule is published under the authority of 15 CFR part 15, subpart B

(sections 15.11 through 15.18), which sets forth the procedures currently applicable to requests submitted to the Department for the testimony of employees and the production of documents for use in legal proceedings to which the Department is not a party. These regulations are also known as “Touhy regulations,” in reference to the case in which the Supreme Court upheld the validity of such agency regulations promulgated pursuant to 5 U.S.C. 301. *See United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

This rulemaking has been determined to be not significant for the purposes of Executive Order (E.O.) 12866. The Department has identified no duplicative, overlapping, or conflicting Federal rules.

Congressional Review Act

The changes in this proposed rule are not expected to result in an annual effect on the economy of \$100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not expected to be considered a “major rule” as defined in 5 U.S.C. 804(2) of the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*).

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act, 5 U.S.C. 605(b), that this proposed rule, if implemented, would not have a significant economic impact on a substantial number of small entities. If implemented, this proposed rule would amend existing regulations in order to clarify the policies, practices, responsibilities, and procedures for Department of Commerce employees related to production of official Departmental documents and testimony by current or former employees as witnesses in legal proceedings. Specifically, the changes in this proposed rule fall into three categories: (1) Clarifying the requirements for individuals or entities making requests for Department information or testimony for use in legal proceedings; (2) refining the procedures the Department uses and elaborating on the policies that support the Department's decision regarding whether to grant

such requests; and (3) making non-substantive clarifying changes in the regulations. This proposed rule would apply to any individual or entity or their legal representative who requests information from the Department or testimony from Departmental employees for use in legal proceedings. There is no requirement that an individual or entity or their legal representative make such a request to the Department unless they seek information or testimony for use in a legal proceeding. If such a request is made, however, the proposed rule would clarify the current regulatory language that describes to whom in the Department the request should be sent, the standards that the request must meet, and the procedures the Department will apply to process the request and determine whether to grant it. The changes proposed in this rule are not expected to have any impact on affected entities. For example, the clarifying changes applicable to the actions of Department employees, reorganization of certain provisions, and harmonization of terminology would have no impact on affected entities seeking information or testimony from the Department for use in legal proceedings. Other proposed changes would impose no additional burden on individuals or entities seeking information or testimony from the Department for use in legal proceedings. For these reasons, this proposed rule, if implemented, would not have a significant economic impact on a substantial number of small entities. Because this proposed rule would not have a significant economic impact on a substantial number of small entities, an initial regulatory flexibility analysis is not required, and none has been prepared.

Paperwork Reduction Act

This proposed rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

Request for Comments

Commerce is seeking comments on this proposed rule on or before October 27, 2021 (see instructions for submitting comments in the **ADDRESSES** section above). All comments received are a part of the public record and will generally be posted without change to <http://regulations.gov>. For posted comments, all personal identifying information (*e.g.*, name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender is publicly accessible. Anonymous comments will be accepted. Enter “N/

A” in the required fields if you wish to remain anonymous. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe portable document format (PDF) only.

List of Subjects in 15 CFR Part 15

Administrative practice and procedure, Courts, Government employees, Legal Proceedings.

Brian D. DiGiacomo,

Assistant General Counsel for Employment, Litigation, and Information, Office of the General Counsel.

For the reasons set out in the preamble, Commerce proposes to amend 15 CFR part 15 as follows:

PART 15—LEGAL PROCEEDINGS

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

Authority: 5 U.S.C. 301; 15 U.S.C. 1501, 1512, 1513, 1515 and 1518; Reorganization Plan No. 5 of 1950; 3 CFR, 1949–1953 Comp., p. 1004; 44 U.S.C. 3101; subpart C is issued under 37 U.S.C. 101, 706; 15 U.S.C. 1673; 42 U.S.C. 665.

Editorial Note: Nomenclature changes to part 15 appear at 62 FR 19669, Apr. 23, 1997.

Subpart B—Testimony by Employees and the Production of Documents in Legal Proceedings

- 2. In subpart B, revise §§ 15.11 through 15.17 to read as follows:

§ 15.11 Scope.

(a) This subpart sets forth the policies and procedures to be followed with respect to the production or disclosure of the testimony of employees and former employees of the Department of Commerce as witnesses in legal proceedings and the production or disclosure of information contained in Department of Commerce documents, or any information acquired by any person while such person was an employee of the Department of Commerce, for use in legal proceedings pursuant to a request, order, or subpoena (collectively referred to in this subpart as a “demand”). No Department employee or former employee shall comply with such a demand without the prior authorization of the General Counsel or appropriate agency counsel, in accordance with this subpart.

(b) This subpart does not apply to any legal proceeding in which an employee is to testify while on leave status, regarding facts or events unrelated to the official business of the Department or the duties of the employee.

(c) This subpart does not apply to any legal proceeding in which the

Department is a party or to subpoenas for testimony or documents received from Congress, a federal agency Inspector General, or a Special Prosecutor.

(d) This subpart does not apply to any demand for testimony of employees and former employees of the United States Patent and Trademark Office (USPTO) or to demands for the production of USPTO documents. The process for any demand for testimony of an employee or for the production of documents of the USPTO can be found at 37 CFR 104.21 through 24, and any such demands must be sent directly to the USPTO.

(e) This subpart in no way affects the rights and procedures governing public access to records pursuant to the Freedom of Information Act, the Privacy Act or the Trade Secrets Act or other federal law restricting the disclosure of information. Moreover, demands in legal proceedings for the production of records, or for the testimony of Department employees regarding information protected by the Privacy Act, 5 U.S.C. 552a, the Trade Secrets Act, 18 U.S.C. 1905, Census data under Title 13, U.S.C., or other confidentiality statutes, must satisfy the requirements for disclosure set forth in those statutes, if any, before the records may be provided or testimony given. The General Counsel or appropriate agency counsel should first determine if there is a legal basis to provide the testimony or records sought under applicable confidentiality statutes before applying the procedures established in this subpart.

(f) This subpart is not intended to be relied upon to, and does not, create any right or benefit, substantive or procedural, enforceable at law by any party against the United States.

§ 15.12 Definitions.

For the purpose of this subpart:

(a) *Agency Counsel* means the Chief Counsel/s or General Counsel/s (or that official’s designee) of a bureau or operating unit within the U.S. Department of Commerce who is the senior legal officer responsible for overseeing legal advice and guidance provided to a particular bureau or operating unit.

(b) *Component* means Office of the Secretary or a bureau or operating unit of the Department as defined in Department Organization Order 1–1.

(c) *Counsel to the Inspector General* means Counsel to the Inspector General of the U.S. Department of Commerce.

(d) *Demand* means a request, order, or subpoena for testimony or documents for use in any legal proceeding.

regardless of whether the United States is a party to the proceeding.

(e) *Department* means the United States Department of Commerce and any of its components, bureaus, or operating units.

(f) *Document or Information* means any record, regardless of format, medium or physical characteristic, document, electronically stored information, paper and other property of the Department, including without limitation, official letters, telegrams, memoranda, reports, studies, writings, emails, calendar and diary entries, text or chat messages, maps, graphs, pamphlets, notes, charts, tabulations, analyses, statistical or informational accumulations, any kind of summaries of meetings and conversations, film impressions, magnetic tapes or sound or mechanical reproductions. Nothing herein shall be interpreted as requiring the creation of a new document to respond to any demand.

(g) *Employee* means any current or former employees or officers of the U.S. Department of Commerce, including any commissioned officer of the National Oceanic and Atmospheric Administration or any other individual who has been appointed by, or is subject to the supervision, jurisdiction, or control of the U.S. Department of Commerce, including contract employees. Contractors may be included.

(h) *General Counsel* means the General Counsel of the U.S. Department of Commerce or other U.S. Department of Commerce employee to whom the General Counsel has delegated authority to act under this subpart.

(i) *Inspector General* means the Inspector General of the U.S. Department of Commerce.

(j) *Legal proceeding* means all pretrial, trial, and post-trial stages of any existing or reasonably anticipated judicial or administrative actions, hearings, investigations, or similar proceedings before administrative, civil, or criminal courts, commissions, boards, or other tribunals, domestic—including local, tribal, state, and federal—foreign, or international. This phrase includes all phases of discovery as well as responses to any formal or informal requests by attorneys, investigators, or other persons not employed by the Department, regarding, testimony, documents, information, or consultation, solicited for use in any legal proceedings.

(k) *Official business* means the authorized business of the U.S. Department of Commerce.

(l) *Secretary* means the Secretary of the U.S. Department of Commerce.

(m) *Testimony* means a statement in any form, including personal appearances before a judge, magistrate, administrative law judge, administrative judge, hearing officer, special master, special counsel, investigating officer or board, or any other court or legal tribunal; declarations made pursuant to 28 U.S.C. 1746; interviews; depositions; telephonic, televised, or videotaped statements; or any responses given during discovery or similar proceedings, which response would involve more than the production of documents.

(n) *United States* means the Federal Government, its departments and agencies, and individuals acting on behalf of the Federal Government.

§ 15.13 Demand for testimony or production of documents: Department procedures.

(a) *General.* No employee, in response to a demand, shall produce any documents or information of the Department, or provide testimony regarding any information relating to, or based upon Department documents, or disclose any information or produce documents acquired or generated as part of the performance of that employee's official duties or because of that employee's official status without the prior authorization of the General Counsel or appropriate agency counsel.

(b) *Notifications.* (1) A demand for the testimony of an employee or for the production of documents of the Department shall be made in writing and addressed to the Assistant General Counsel for Employment, Litigation, and Information, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Room 5896, Washington, DC 20230; or by email to: Touhy@doc.gov; or to appropriate agency counsel.

(2) The process for any demand for testimony of an employee or for the production of documents of the USPTO can be found at 37 CFR 104.21 through 24, and any such demands should be sent directly to the USPTO, in accordance with § 15.11(d) of this subpart.

(c) *Employee Procedure.* Whenever a Department employee receives an inquiry or demand for testimony or production of documents, that employee shall not respond, and shall immediately notify the Office of the Assistant General Counsel for Employment, Litigation, and Information as provided above, or appropriate agency counsel, and provide a copy of the demand. An employee may not answer inquiries from a person not employed by the Department regarding testimony or documents subject to a demand or a

potential demand under the provisions of this subpart without the approval of the General Counsel or appropriate agency counsel.

(d) *Subpoenas.* A subpoena for testimony or production of documents by a Department employee must be served in person, at the office or home, or by mail in accordance with the Federal Rules of Civil or Criminal Procedure or applicable state procedure. Service solely by electronic means is not authorized. If service is made upon anyone other than the General Counsel or appropriate agency counsel, then a copy of the subpoena shall also be contemporaneously sent to the General Counsel at the appropriate addresses in subsection (b) above, or appropriate agency counsel.

(1) An employee who receives a such a subpoena shall not respond and shall immediately forward the subpoena to the Office of the Assistant General Counsel for Employment, Litigation, and Information or the appropriate agency counsel. The General Counsel or appropriate agency counsel will determine the extent to which a Department employee will comply with the subpoena.

(2) If the General Counsel or appropriate agency counsel determines that an employee should not comply with a properly-served subpoena, the General Counsel or agency counsel will attempt to have the subpoena withdrawn or modified. If this cannot be done with regard to a subpoena for documents, the Department will provide the tribunal with an objections letter or other notification that the documents will not be produced. If this cannot be done with regard to a subpoena for testimony, the General Counsel or appropriate agency counsel will attempt to obtain U.S. Department of Justice representation for the employee and move to have the subpoena modified or quashed. If, because of time constraints, this is not possible prior to the compliance date specified in the subpoena, the employee should appear at the time and place set forth in the subpoena. If legal counsel cannot appear on behalf of the employee, the employee should produce a copy of the Department's regulations and inform the legal tribunal that the employee has been advised by counsel not to provide the requested testimony and/or produce documents. If the legal tribunal rules that the demand in the subpoena must be complied with, the employee shall respectfully decline to comply with the demand. *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

§ 15.14 Demand for testimony or production of documents in matters in which the United States is not a party.

(a) *General.* Every demand for testimony or documents in a legal matter in which the United States is not a named party shall be made in writing, delivered in accordance with section 15.13(b) of this subpart no later than 30 days before the document or testimony is required, and shall be accompanied by an affidavit or written declaration under 28 U.S.C. 1746, or, if an affidavit or declaration is not feasible, a written statement setting forth:

- (1) The title of the legal proceeding,
- (2) The forum;
- (3) The requesting party's interest in the legal proceeding;
- (4) The reason for the demand and the relevance of the request to the legal proceeding;
- (5) A showing that the desired testimony or document is not reasonably available from any other source; and
- (6) If testimony is requested, the intended use of the testimony; a general summary of the desired testimony; the time that will be required to prepare for, travel to, and present testimony; and a showing that no document could be provided and used in lieu of testimony, including from opposing parties via discovery proceedings.

(b) *Purpose.* The purpose of this requirement is to assist the General Counsel or appropriate agency counsel in making an informed decision regarding whether testimony or the production of a document(s) should be authorized, in accordance with § 15.16 of this subpart. Any authorization for testimony by an employee of the Department shall be limited to the scope of the demand as summarized in the statement or as negotiated in subparagraph (e) of this section.

(c) *Prior Authorization.* A certified copy of a document that has been authorized pursuant to § 15.16(a) for use in a legal proceeding may be provided upon written request and payment of applicable fees. Written requests for certification must be addressed to the agency counsel for the component having possession, custody, or control of the document. The requestor must provide the agency with information regarding the prior authorization for release of the requested document pursuant to § 15.16(a), including date of release and parties to whom the document was released.

(d) *Secretary's Authority.* The Secretary retains the authority to authorize and direct testimony in those cases where a statute or Presidential

order mandates a personal decision by the Secretary.

(e) *Consultation.* The General Counsel or appropriate agency counsel may consult or negotiate with an attorney for a party, or with the party if not represented by an attorney, to refine or limit a demand so that compliance is less burdensome or seek additional information about the demand necessary to make the determination required by paragraph (b) of this section. Failure of the attorney or party to cooperate in good faith to enable the General Counsel or the appropriate agency counsel to make an informed decision under this subpart may serve, where appropriate, as a basis for a determination not to comply with the demand. In addition, the General Counsel or appropriate agency counsel may impose further conditions or restrictions on the production of any document or testimony when that is in the best interests of the United States.

(f) *Fact witness.* If an employee is authorized to give testimony in a legal proceeding not involving the United States, the testimony, if otherwise proper, shall be limited to facts within the personal knowledge of the employee that are not classified, privileged, or protected from disclosure under applicable law or regulation. If asked to provide factual testimony that the employee believes may be classified, privileged, or protected from disclosure under applicable law or regulation, then the witness shall:

- (1) Respectfully decline to answer on the grounds that such testimony is prohibited; and
- (2) Request an opportunity to consult with the General Counsel or appropriate agency counsel.

(g) *Expert or Opinion Witness.*

(1) Current employees, with or without compensation, shall not provide expert or opinion testimony in any legal proceedings regarding Department information, subjects, or activities except on behalf of the United States or a party represented by the United States Department of Justice. However, upon a showing by the requester that there are exceptional circumstances and that the anticipated testimony will not be adverse to the interests of the Department or the United States, the General Counsel, or appropriate agency counsel after consultation with the Office of the General Counsel, may grant special authorization in writing for a current employee to appear and give the expert or opinion testimony.

(i) If, while testifying in any legal proceeding, an employee is asked for expert or opinion testimony regarding

official information, subjects or activities, which testimony has not been approved in advance in accordance with the regulations in this subpart, the witness shall:

(A) Respectfully decline to answer on the grounds that such expert or opinion testimony is forbidden by the regulations in this subpart;

(B) Request an opportunity to consult with the General Counsel or appropriate agency counsel before giving such testimony; and

(C) Explain that upon such consultation, approval for such testimony may be provided.

(ii) If the body conducting the proceeding then orders the witness to provide expert or opinion testimony regarding official information, subjects, or activities without the opportunity to consult with either the General Counsel or appropriate agency counsel, the witness shall respectfully refuse to provide such testimony. *See United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

(iii) If an employee is unaware of the regulations in this subpart and provides expert or opinion testimony regarding official information, subjects, or activities in a legal proceeding without the aforementioned consultation, the witness must, as soon as possible after testifying, inform the General Counsel or appropriate agency counsel that such testimony was given and provide a written summary of the expert or opinion testimony provided.

(2) Former employees may provide opinion or expert testimony if: (i) The testimony does not involve non-public facts, information, or documents about a particular matter that were acquired by the former employee during the performance of their employment with the United States; and (ii) the involvement of the former employee in the proceeding as a witness complies with 18 U.S.C. 207 and applicable post-employment Ethics rules. *See* 5 CFR 2641. Former employees offering expert or opinion testimony and those seeking such testimony from former employees, must confer with the General Counsel or appropriate agency counsel to ascertain if the prospective expert or opinion testimony is consistent with this subpart.

(h) A decision under this subpart to comply or not to comply with a demand is neither an assertion or waiver of privilege, nor an assertion of lack of relevance or technical deficiency, nor does it reflect any other ground for noncompliance.

(i) The General Counsel or appropriate agency counsel may waive any requirements set forth under this

section to the extent allowed by law, when circumstances warrant.

§ 15.15 Demand for testimony or production of documents in matters in which the United States is a party.

If a demand is received pertaining to a legal matter in which the United States but not the Department is a named party, or where a party other than the Department is represented by the Department of Justice, the following rules apply.

(a) *Demand not from the United States.* For demands for documents from, or testimony of an employee of the Department, from an entity other than the United States pursuant to a legal proceeding in which the United States is a party, the demand must be in writing and signed, delivered in accordance with section 15.13(b), setting forth the information required in section 15.14(a), and copied to the attorneys of record representing or acting under the authority of the United States in the legal proceeding. Upon receipt of the demand, the General Counsel or appropriate agency counsel shall promptly contact the appropriate Department of Justice office to coordinate any response in accordance with applicable federal or state rules of civil procedure governing discovery matters.

(b) *Demand from the United States.* When a demand for documents from, testimony of, or consultation with an employee of the Department comes from an attorney representing or acting under the authority of the United States concerning a legal proceeding in which the United States is a party, every such demand should be accompanied by a statement setting forth the legal proceeding, the forum, the United States' interest in the legal proceeding, and the relevance and use of the requested documents or testimony. The purpose of this requirement is to assist the General Counsel or the appropriate agency counsel in making all necessary arrangements to facilitate the demand on behalf of the United States. Where appropriate, the General Counsel or appropriate agency counsel may require reimbursement to the Department of the expenses associated with a Department employee giving testimony or providing consultation on behalf of the United States.

(c) *Expert or Opinion Witness.* In a legal proceeding in which the United States is a party, a current Department employee may not testify as an expert or opinion witness for any other party other than the United States. However, a former employee may provide opinion or expert testimony for a party other

than the United States if: (i) The testimony does not involve facts, information, or documents about a particular matter that were acquired by the former employee during the performance of their official duties as an employee of the United States; and (ii) the involvement of the former employee in the proceeding as a witness complies with applicable post-employment conflict of interest laws. *See* 18 U.S.C. 207 and 5 CFR 2641. A former employee offering expert or opinion testimony or consulting, and those seeking such testimony from a former employee, shall confer with the General Counsel or appropriate agency counsel to ascertain if the prospective expert or opinion testimony or consulting is consistent with this subpart.

§ 15.16 Demand for testimony or production of documents: Department Policy and Considerations.

(a) *Decision.* In deciding whether to authorize a demand for testimony or documents under this subpart, the General Counsel or appropriate agency counsel shall consider whether the disclosure or testimony is in the interests of the Department. The following factors should be considered:

(1) Conserving the time of Department employees for conducting official business;

(2) Minimizing the possibility of involving the Department in controversial issues that are not related to the Department's mission or matters that do not further the Department's mission;

(3) Preventing the possibility that the public will misconstrue variances between personal opinions of Department employees and official Department policy;

(4) Avoiding spending the time and money of the United States for private purposes;

(5) Preserving the integrity of the administrative or judicial process;

(6) Protecting classified, confidential, or controlled unclassified information, and the deliberative process of the Department;

(7) Preventing the appearance of improperly favoring one litigant over another;

(8) Avoiding the denial of a party's constitutional or statutory rights;

(9) Whether such disclosure is appropriate under the rules of procedure governing the case or matter in which the demand arose;

(10) Whether disclosure is appropriate under the relevant substantive law concerning privilege; and

(11) Any other issue that is relevant to the decision.

(b) *Non-disclosure Factors.* Demands for testimony or documents in response to which disclosure will not be made by any Department official include, but are not limited to, those demands with respect to which any of the following factors exist:

(1) Disclosure is restricted by statute or regulation, or would violate a rule of procedure, executive order, policy, or an applicable government directive;

(2) Disclosure would reveal classified or controlled unclassified information, unless appropriately declassified or decontrolled by the originating agency;

(3) Disclosure would reveal a confidential source or informant, unless the investigative agency and the source or informant have no objection;

(4) Disclosure would reveal investigatory records compiled for law enforcement purposes and would interfere with enforcement proceedings or disclose investigative techniques and procedures, the effectiveness of which would thereby be impaired.

(5) Disclosure would improperly reveal trade secrets or disclose information protected by law, a non-disclosure agreement, or court order without authorized consent;

(6) Disclosure would be unduly costly, burdensome, or otherwise inappropriate under applicable court rules;

(7) Disclosure would involve the Department in controversial issues that are not related to the Department's mission or issues that do not further the Department's mission; or

(8) Disclosure would involve scientific or expert opinion on research that is controversial or contrary to Department policy, or would result in burdensome repetition of similar testimony in subsequent proceedings.

§ 15.17 Subpoenas and demands served upon employees or former employees of the Office of the Inspector General.

Notwithstanding the requirements set forth in §§ 15.11 through 15.16, this subpart is applicable to demands served on employees or former employees of the Office of the Inspector General (OIG), except that wherever in §§ 15.11 through 15.16 there appear the phrases General Counsel, Agency Counsel, or Assistant General Counsel for Employment, Litigation, and Information, there shall be substituted in lieu thereof the Inspector General or Counsel to the Inspector General. In addition, the appropriate address for notifications specified in § 15.13(b) pertaining to employees and former employees covered under this section is Office of the Inspector General, U.S. Department of Commerce, 1401

Constitution Avenue NW, Room 7896,
Washington, DC 20230.

[FR Doc. 2021-20651 Filed 9-24-21; 8:45 am]

BILLING CODE 3510-BW-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FF09E21000 FXES11110900000 212]

Endangered and Threatened Wildlife and Plants; 17 Species Not Warranted for Listing as Endangered or Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notification of findings.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce findings that 17 species are not warranted for listing as endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). After a thorough review of the best available scientific and commercial information, we find that it is not warranted at this time to list Amargosa tryonia (*Tryonia variegata*), Ash Meadows pebblesnail (*Pyrgulopsis erythropoma*), boat-shaped bugseed (*Corispermum navicula*), Burrington jumping-slug (*Hemphillia burringtoni*), crystal springsnail (*Pyrgulopsis crystalis*), Dalles sideband (*Monadenia fidelis minor*), distal-gland springsnail (*Pyrgulopsis nanus*), early dark blue butterfly (*Euphilotes ancilla purpura*), Fairbanks springsnail (*Pyrgulopsis fairbanksensis*), late dark blue butterfly

(*Euphilotes ancilla cryptica*), median-gland springsnail (*Pyrgulopsis pisteri*), minute tryonia (*Tryonia ericae*), Point of Rocks tryonia (*Tryonia elata*), southern rubber boa (*Charina umbratica*), southwest Nevada pyrg (*Pyrgulopsis turbatrix*), sportinggoods tryonia (*Tryonia angulata*), and Virgin spinedace (*Lepidomeda mollispinis mollispinis*). However, we ask the public to submit to us at any time any new information relevant to the status of any of the species mentioned above or their habitats.

DATES: The findings in this document were made on September 27, 2021.

ADDRESSES: Detailed descriptions of the bases for these findings are available on the internet at <http://www.regulations.gov> under the following docket numbers:

Species	Docket No.
Amargosa tryonia	FWS-R8-ES-2021-0077
Ash Meadows pebblesnail	FWS-R8-ES-2021-0078
boat-shaped bugseed	FWS-R6-ES-2021-0079
Burrington jumping-slug	FWS-R1-ES-2021-0080
crystal springsnail	FWS-R8-ES-2021-0081
Dalles sideband	FWS-R1-ES-2021-0082
distal-gland springsnail	FWS-R8-ES-2021-0083
early dark blue butterfly	FWS-R8-ES-2021-0084
Fairbanks springsnail	FWS-R8-ES-2021-0085
late dark blue butterfly	FWS-R8-ES-2021-0086
median-gland springsnail	FWS-R8-ES-2021-0087
minute tryonia	FWS-R8-ES-2021-0088
Point of Rocks tryonia	FWS-R8-ES-2021-0089
southern rubber boa	FWS-R8-ES-2015-0119
southwest Nevada pyrg	FWS-R8-ES-2021-0090
sportinggoods tryonia	FWS-R8-ES-2021-0091
Virgin spinedace	FWS-R6-ES-2015-0121

Those descriptions are also available by contacting the appropriate person as specified under **FOR FURTHER INFORMATION CONTACT**. Please submit any

new information, materials, comments, or questions concerning this finding to the appropriate person, as specified

under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT:

Species	Contact information
Amargosa tryonia, Ash Meadows pebblesnail, crystal springsnail, distal-gland springsnail, Fairbanks springsnail, median-gland springsnail, minute tryonia, Point of Rocks tryonia, southwest Nevada pyrg, sportinggoods tryonia, early dark blue butterfly, late dark blue butterfly.	Glen Knowles, Field Supervisor, Southern Nevada Fish and Wildlife Office, (702) 515-5244.
boat-shaped bugseed	Ann Timberman, Field Supervisor, Colorado Field Office, (970) 628-7181.
Burrington jumping-slug	Brad Thompson, State Supervisor, Washington Fish and Wildlife Office, (360) 753-9440.
Dalles sideband	Paul Henson, State Supervisor, Oregon Fish and Wildlife Office, (503) 231-6179.
southern rubber boa	Scott Sobiech, Field Supervisor, Carlsbad Fish and Wildlife Office, (760) 431-9440.
Virgin spinedace	Yvette Converse, Field Supervisor, Utah Field Office, (801) 975-3330.

If you use a telecommunications device for the deaf (TDD), please call the Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION:

Background

Under section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*), we are required to make a finding whether or not a

petitioned action is warranted within 12 months after receiving any petition for which we have determined contains substantial scientific or commercial

information indicating that the petitioned action may be warranted (“12-month finding”). We must make a finding that the petitioned action is: (1) Not warranted; (2) warranted; or (3) warranted, but precluded by other listing activity. We must publish a notification of these 12-month findings in the **Federal Register**.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations at part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Lists of Endangered and Threatened Wildlife and Plants (Lists). The Act defines “species” as including any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature. The Act defines “endangered species” as any species that is in danger of extinction throughout all or a significant portion of its range (16 U.S.C. 1532(6)), and “threatened species” as any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). Under section 4(a)(1) of the Act, a species may be determined to be an endangered species or a threatened species because of any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

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) does not necessarily mean that the species meets the statutory definition of an “endangered species” or a “threatened species.” In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all 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. The Secretary determines whether the species meets the Act’s definition of an “endangered species” or a “threatened species” only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term “foreseeable future,” which appears in the statutory definition of “threatened species.” Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term “foreseeable future” extends only so far into the future as the Service can reasonably determine that both the future threats and the species’ responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. “Reliable” does not mean “certain”; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species’ likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species’ biological response include species-specific factors such as lifespan, reproductive rates or productivity,

certain behaviors, and other demographic factors.

In conducting our evaluation of the five factors provided in section 4(a)(1) of the Act to determine whether Amargosa tryonia, Ash Meadows pebblesnail, Burrington jumping-slug, crystal springsnail, Dalles sideband, distal-gland springsnail, early dark blue butterfly, Fairbanks springsnail, late dark blue butterfly, median-gland springsnail, minute tryonia, Point of Rocks tryonia, southern rubber boa, southwest Nevada pyrg, sportsgoods tryonia, or Virgin spinedace meet the Act’s definition of “endangered species” or “threatened species,” we considered and thoroughly evaluated the best scientific and commercial information available regarding the past, present, and future stressors and threats. In conducting our taxonomic evaluation of boat-shaped bugseed, we determined that it does not meet the definition of a “species” under the Act, and, as a result, we concluded that boat-shaped bugseed is not a listable entity. We reviewed the petitions, information available in our files, and other available published and unpublished information for all of these species. Our evaluation may include information from recognized experts; Federal, State, and Tribal governments; academic institutions; foreign governments; private entities; and other members of the public.

The species assessment forms for these species contain more detailed biological information, a thorough analysis of the listing factors, a list of literature cited, and an explanation of why we determined that these species do not meet the Act’s definition of an “endangered species” or a “threatened species.” A thorough review of the taxonomy, life history, and ecology of the Amargosa tryonia, Ash Meadows pebblesnail, Burrington jumping-slug, crystal springsnail, Dalles sideband, distal-gland springsnail, early dark blue butterfly, Fairbanks springsnail, late dark blue butterfly, median-gland springsnail, minute tryonia, Point of Rocks tryonia, southern rubber boa, southwest Nevada pyrg, sportsgoods tryonia, and Virgin spinedace is presented in the species’ Species Status Assessment reports. The species assessment form for boat-shaped bugseed contains more detailed taxonomic information, a list of literature cited, and an explanation of why we determined that boat-shaped bugseed does not meet the Act’s definition of a “species.” This supporting information can be found on the internet at <http://www.regulations.gov> under the

appropriate docket number (see **ADDRESSES**, above). The following are informational summaries for the findings in this document.

Amargosa Tryonia, *Ash Meadows Pebblesnail*, *Crystal Springsnail*, *Distal-Gland Springsnail*, *Fairbanks Springsnail*, *Median-Gland Springsnail*, *Minute Tryonia*, *Point of Rocks Tryonia*, *Southwest Nevada Pyrg*, and *Sportinggoods Tryonia*

Previous Federal Actions

On February 17, 2009, we received a petition from the Center for Biological Diversity (CBD) requesting that the Service list 42 species of springsnails from the Great Basin and Mojave ecosystems in Nevada, Utah, and California as endangered or threatened species, and designate critical habitat for the springsnails. The petition included *Amargosa tryonia*, *Ash Meadows pebblesnail*, *crystal springsnail*, *distal-gland springsnail*, *Fairbanks springsnail*, *median-gland springsnail* (as “median gland Nevada pyrg”), *minute tryonia*, *Point of Rocks tryonia*, *southwest Nevada pyrg* (as “southeast Nevada pyrg”), and *sportinggoods tryonia*. On September 13, 2011, we published in the **Federal Register** (76 FR 56608) a 90-day finding in which we announced that the petition contained substantial information indicating listing of 32 of the petitioned species, including these 10 springsnails, may be warranted. This document announces the 12-month finding on the February 17, 2009, petition to list the *Amargosa tryonia*, *Ash Meadows pebblesnail*, *crystal springsnail*, *distal-gland springsnail*, *Fairbanks springsnail*, *median-gland springsnail*, *minute tryonia*, *Point of Rocks tryonia*, *southwest Nevada pyrg*, and *sportinggoods tryonia* under the Act.

Summary of Finding

The 10 springsnail species are in the genus *Pyrgulopsis* or *Tryonia* of the Cochliopidae family. In general, the 10 species are morphologically similar with hardened shells and soft anatomy, and they are differentiated based on subtle morphological characteristics. They are small in size, only a few millimeters in length and width, and have limited ability or tendency to move. These springsnails are herbivores or detritivores that primarily graze on the periphyton (freshwater organisms attached or clinging to plants) of exposed surfaces of aquatic plants and substrates in the small springs they inhabit. Nine of the springsnails occur in desert aquifer springs comprised of

small aquatic and riparian systems as surface flow maintained by groundwater; each spring is uniquely influenced by aquifer geology, morphology, discharge rates, and regional precipitation. The southwest Nevada pyrg occurs in desert springs that are primarily perennial mountain block aquifer springs that are less likely to be influenced by groundwater withdrawals.

All of the species excluding the southwest Nevada pyrg occur only on Ash Meadows National Wildlife Refuge (NWR) in the Amargosa Valley (Amargosa Desert Hydrographic Area) in Nye County, Nevada. However, additional surveys are necessary to determine if *Amargosa tryonia* occurs in more locations on the refuge and on private lands in Shoshone and Tecopa, California. In contrast, the southwest Nevada pyrg is widespread across southeastern California (Inyo and San Bernardino Counties) and southwestern Nevada (Nye and Clark Counties). Spring conditions that are most critical in influencing the resource needs of all life stages of the 10 springsnails include water quality (e.g., appropriate water temperature, dissolved oxygen levels, conductivity, pH), presence of aquatic vegetation and appropriate substrate (both of which can be variable), the continuity of free-flowing water, and adequate spring discharge.

We carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the springsnails, and we evaluated all relevant factors under the five listing factors, including any regulatory mechanisms and conservation measures addressing these threats. Historically and through to the present, the 10 springsnail species and their habitats were impacted to varying degrees by one or more of the following threats: Predation and competition, vegetation and soil disturbance, spring modification, and groundwater pumping. Sources of these threats include invasive, nonnative and native species; roads; wildfire; grazing and browsing by ungulates; recreation; herbicides; and human development. The primary threat currently and into the future is spring modifications resulting from potential groundwater pumping or altered precipitation/temperature from climate change, both of which could affect the availability of adequate water and flow. The species' locations are as follows:

- *Amargosa tryonia* currently occurs in 12 spring locations (some of which are comprised of multiple, clustered springs described as spring provinces). The majority of these spring locations

are found within protected lands on Ash Meadows NWR (11 locations), with the remaining location at Devils Hole at Death Valley National Park.

- *Ash Meadows pebblesnail* currently occurs on Ash Meadows NWR in the large Kings Pool and at four small, clustered springs within the Point of Rocks Spring Province.

- *Crystal springsnail* occurs in a single desert spring known as the Crystal Spring on Ash Meadows NWR.

- *Distal-gland springsnail* currently occurs on Ash Meadows NWR in the following three springs/spring provinces that are centrally located on the refuge: Collins Ranch Spring, Five Springs Province, and Mary Scott Spring.

- *Fairbanks springsnail* occurs in a single desert spring known as the Fairbanks Spring on Ash Meadows NWR.

- *Median-gland springsnail* is centrally located in the Warm Springs area of Ash Meadows NWR in three springs (Marsh Spring, North Scruggs Spring, and School Spring).

- *Minute tryonia* occurs in a single desert spring known as North Scruggs Spring within the Warm Springs area of Ash Meadows NWR.

- *Point of Rocks tryonia* occurs on Ash Meadows NWR within the Point of Rocks Spring Province, which is comprised of six small, geographically clustered springs, four of which are occupied by the species.

- *Sportinggoods tryonia* is located within three large springs on the Ash Meadows NWR (Big Spring, Crystal Pool, and Fairbanks Pool).

- Southwest Nevada pyrg occurs within 36 springs or spring provinces in 8 different geographic areas (9 different hydrologic subbasins, which are analogous to medium-sized river basins) in southwest Nevada and southeast California. Spring locations and ownership across its range include primarily Federal lands at Death Valley National Park, Bureau of Land Management lands (Red Rock Canyon National Conservation Area, Darwin Falls Wilderness, Argus Range Wilderness, Surprise Canyon Wilderness, Pleasant Canyon), U.S. Forest Service lands (Spring Mountains National Recreation Area, Big Bear Lake Range Station and Mill Creek Canyon in the San Bernardino National Forest), Department of Defense lands (China Lake Naval Weapons Center), and private lands in both Nevada and California.

The best available information indicates an overall high likelihood that the 10 springsnails will continue to maintain resilient populations in the foreseeable future given the significant

conservation afforded to them across the majority of the springs/populations, no information suggesting new groundwater pumps or increased impacts from groundwater pumping compared to current levels, and climate models showing increased precipitation into the future across the species' ranges. Coupled with aquifer rate of recharge information, there is a high likelihood that adequate levels of water and flow (as well as the other resource needs of the species) would be available in the foreseeable future. We considered these primary threats cumulatively with the additional non-primary threats described above (e.g., invasive species), in our determination.

Therefore, we find that listing the Amargosa tryonia, Ash Meadows pebblesnail, crystal springsnail, distalgland springsnail, Fairbanks springsnail, median-gland springsnail, minute tryonia, Point of Rocks tryonia, southwest Nevada pyrg, and sportinggoods tryonia as endangered species or threatened species under the Act is not warranted. Furthermore, we did not find any evidence of a concentration of threats at a biologically meaningful scale in any portion of the species' range. A detailed discussion of the basis for this finding can be found in the species assessment forms for these 10 species and other supporting documents (see **ADDRESSES**, above).

Boat-Shaped Bugseed

Previous Federal Actions

On July 30, 2007, the Service received a petition from Forest Guardians (now WildEarth Guardians) requesting that the Service list 206 species the Mountain-Prairie Region, including the boat-shaped bugseed (formerly *Corispermum navicula*), as endangered or threatened species, and designate critical habitat, under the Act.

On August 18, 2009, the Service published a 90-day finding (74 FR 41649) indicating that listing may be warranted for 29 species, including the boat-shaped bugseed. As a result, the Service initiated a status review for the boat-shaped bugseed. This document announces the 12-month finding on the July 30, 2007, petition to list the boat-shaped bugseed under the Act.

Summary of Finding

We have carefully assessed the best scientific and commercial information available regarding the boat-shaped bugseed and evaluated the petition's claims that the species warrants listing under the Act. Genetic and morphometric analyses indicate that the boat-shaped bugseed is not a distinct

species or subspecies. The boat-shaped bugseed is not genetically or morphologically distinguishable from other bugseeds, including the more wide-ranging American bugseed (*C. americanum*). Therefore, the boat-shaped bugseed is not a valid taxonomic entity, does not meet the definition of a "species" under the Act, and, as a result, does not warrant listing under the Act. A detailed discussion of the basis for this finding can be found in the boat-shaped bugseed species assessment form and other supporting documents (see **ADDRESSES**, above).

Burrington Jumping-Slug

Previous Federal Actions

On March 17, 2008, we received a petition from CBD, Conservation Northwest, the Environmental Protection Information Center, the Klamath-Siskiyou Wildlands Center, and Oregon Wild, requesting that the Service list 32 species and subspecies of mollusks in the Pacific Northwest, including the Burrington jumping-slug, as endangered or threatened species under the Act. The petition also requested that the Service designate critical habitat concurrent with listing. On October 5, 2011, the Service published a 90-day finding that the petition presented substantial scientific or commercial information indicating that Burrington jumping-slug (also known as the "keeled jumping-slug") may be warranted for listing (76 FR 61826). This document announces the 12-month finding on the March 17, 2008, petition to list the Burrington jumping-slug under the Act.

Summary of Finding

Burrington jumping-slugs are small terrestrial gastropods that range throughout the western portions of British Columbia, Washington, and Oregon. The species is known from approximately 2,350 records, most of which are a result of surveys conducted prior to vegetation management, thinning, and timber projects on Federal lands. In British Columbia, documented Burrington jumping-slug occurrences are limited to the southern portion of Vancouver Island. In Washington, they occur on the Olympic Peninsula and along the Pacific coast. In Oregon, they occur primarily in the Coast Range.

The species inhabits moist, cool, and shady forest floors where there is sufficient shade and downed, decaying logs and leaf litter. They are found in a variety of forest types including dense old-growth rainforests, riparian areas, late-successional and old-growth coniferous forests, mixed coniferous

forests, and areas densely forested with Pacific dogwood (*Cornus nuttallii*). Red alder (*Alnus rubra*), bigleaf maple (*Acer macrophyllum*), vineleaf maple (*Acer circinatum*), and Pacific dogwood are consistently associated with the understory and mid-story components of suitable habitat for the species.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Burrington jumping-slug, and evaluated all relevant factors under the five listing factors, including any regulatory mechanisms and conservation measures addressing these stressors. The primary stressors affecting the Burrington jumping-slug's biological status include habitat loss and fragmentation due to forest management and development, and climate-mediated changes in temperature and wildfire risk. Currently, the species has more than 50 populations in good or moderate condition that are distributed across its historical range and occupy a diversity of ecological settings. The projected effects of habitat loss, rising temperatures, and increased fire risk are likely to reduce the number of populations in good or moderate condition and lead to some additional extirpations of populations. However, due to the number and spatial heterogeneity of remaining populations, the species is projected to maintain adequate levels of resiliency. Given the species' continued widespread distribution and its ecological and genetic diversity, we project that it will also maintain adequate redundancy and representation rangewide in the foreseeable future. Furthermore, we did not find any evidence of a concentration of threats at any biologically meaningful scale in any portion of the species' range.

Therefore, we find that listing the Burrington jumping-slug as an endangered species or threatened species under the Act is not warranted. A detailed discussion of the basis for this finding can be found in the Burrington jumping-slug SSA report and other supporting documents (see **ADDRESSES**, above).

Dalles Sideband

Previous Federal Actions

On March 17, 2008, we received a petition from CBD, Conservation Northwest, the Environmental Protection Information Center, the Klamath-Siskiyou Wildlands Center, and Oregon Wild, requesting that the Service list 32 species and subspecies of mollusks in the Pacific Northwest,

including the Dalles sideband, as endangered or threatened under the Act. The petition also requested that the Service designate critical habitat concurrent with listing. On October 5, 2011, the Service published a 90-finding that the petition presented substantial scientific or commercial information indicating that the Dalles sideband may be warranted for listing (76 FR 61826). To inform our status review, we completed an SSA for the Dalles sideband. This document announces the 12-month finding on the March 17, 2008, petition to list the Dalles sideband under the Act.

Summary of Finding

The Dalles sideband is a small, terrestrial snail that is a subspecies of the Pacific sideband snail (*Monadenia fidelis*), with a known range east of the Cascade Mountains in Oregon and Washington, primarily along the Columbia River corridor, extending east to the mouth of the John Day River. Occurrences have been documented near The Dalles, Oregon, with more recent detections on the Mount Hood National Forest in Oregon and the Gifford Pinchot National Forest in Washington. The Dalles sideband has been identified in Wasco, Hood River, and Sherman Counties in Oregon, and Skamania, Lewis, and Klickitat Counties in Washington. The majority of known occurrences are a result of surveys conducted prior to vegetation management, thinning, and timber projects on Federal lands.

The Dalles sideband inhabits forested environments, particularly those near talus slopes and/or in areas containing a high concentration of woody debris, leaves, or other refugia. They also live in cool, moist areas near springs and riparian areas. While the specific diet of the Dalles sideband is not known, other members of its genus feed on various plant material, roots, fungus, microorganisms, and other organic matter.

We carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Dalles sideband, and we evaluated all relevant factors under the five listing factors, including any regulatory mechanisms and conservation measures addressing these stressors. The primary stressors affecting the Dalles sideband's biological status include habitat loss and fragmentation due to forest management, and the climate-mediated risk of drought and wildfire. Currently, the subspecies is known from 23 resiliency units (delineated from 174 occurrence records), the majority of

which are in high condition, with the remainder in moderate condition. These resiliency units are distributed across the historical range of the subspecies and occupy a diversity of ecological settings. We considered three plausible future scenarios that included projected changes in forest management, and the risk of drought and wildfire, as influenced by climate change, and how these threats would impact Dalles sideband habitat and population connectivity. We determined that these threats are likely to reduce the number of Dalles sideband populations in high or moderate condition, and may lead to some populations becoming extirpated in the future. However, our analysis indicates that even with the projected decline in habitat quality, and by proxy the populations, the subspecies will maintain adequate levels of resiliency across most remaining populations, and adequate redundancy and representation rangewide, to maintain the subspecies' viability in the foreseeable future.

Therefore, we find that listing the Dalles sideband as an endangered or threatened species under the Act is not warranted. Furthermore, we did not find any evidence of a concentration of threats at a biologically meaningful scale in any portion of the species' range. A detailed discussion of the basis for this finding can be found in the Dalles sideband species assessment form and other supporting documents (see **ADDRESSES**, above).

Early Dark Blue Butterfly and Late Dark Blue Butterfly

Previous Federal Actions

On October 6, 2011, we received a petition, dated September 30, 2011, from WildEarth Guardians to list the two dark blue butterfly subspecies as endangered or threatened under the Act. On August 7, 2012, we published a 90-day finding stating that the petition presented substantial information indicating that listing the dark blue butterflies (as "two Spring Mountains dark blue butterflies") may be warranted (77 FR 47003). This document announces our 12-month finding on the September 30, 2011, petition to list the two dark blue butterfly subspecies.

Summary of Finding

The Spring Mountains dark blue butterflies are two subspecies of the Ancilla dotted blue butterfly (*Euphilotes ancilla*) found in the Spring Mountains in Clark County in southwestern Nevada. The two subspecies have no widely recognized common names, so we refer to them as the early subspecies

(*E. a. purpura*) and the late subspecies (*E. a. cryptica*) to coincide with their respective flight periods.

The Spring Mountains dark blue butterflies are distributed across the Spring Mountains above an elevation of 1,600 meters (5,250 feet). The late dark blue butterfly is distributed throughout the Spring Mountains, and the early dark blue butterfly has a narrower range restricted to the northern third of the Spring Mountains. The two subspecies overlap with each other in three locations in this part of their range. The early dark blue butterfly has a flight period from May to June, and the late dark blue butterfly has a flight period from late June to early September. Both subspecies use varieties of sulphur-flowered buckwheats (*Eriogonum umbellatum*) as their host plants.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the early and late dark blue butterflies, and we evaluated all relevant factors under the five listing factors, including any regulatory mechanisms and conservation measures addressing these threats. The primary threats affecting both the early and the late dark blue butterflies' biological status include fire, herbivory of host plants, drought, and climate change. If the magnitude or frequency of fire increased with less time for habitat to recover, the effects of fire on dark blue butterflies and their habitat could become more severe. However, current models show that fire risk in the Spring Mountains is moderate to low, and we do not have any information that fires will increase in magnitude into the foreseeable future. As a result of climate change in the Spring Mountains, droughts could become more frequent, and host plants will likely shift upward in elevation. However, both subspecies of dark blue butterfly already occur at a wide elevational range, which may allow them to respond by moving upslope to more favorable areas. Adult dark blue butterflies are capable of finding diffuse and small patches of flowers, which allows them to match with habitat over a wide range of elevations, allowing for survival during climatic fluctuations. Additionally, although herbivory by native species and feral horses is occurring at most dark blue butterfly locations, the magnitude of impacts is low.

Currently, all 9 populations of early dark blue butterflies and 30 of 33 populations of late dark blue butterflies are experiencing low or moderate exposure to threats. In all future scenarios, we expect that populations will continue to experience only low or

moderate levels of threat in the foreseeable future. In scenarios for the two subspecies, the resiliency, redundancy, and representation of both may decrease depending on the severity of climate change as the risk of drought and catastrophic fires increases the potential for population extirpation. The early dark blue butterfly is at greater risk because it occurs at only nine locations. However, dark blue butterflies display adaptive capacity in their ability to recolonize areas following disturbance, and as previously discussed, they likely have the ability to shift upslope in response to climate change. Overall, even if some reductions occur, we expect that the subspecies will maintain enough viability that they will not be likely to be endangered in the foreseeable future.

Therefore, we find that listing the early dark blue butterfly as an endangered species or threatened species under the Act is not warranted. We also find that listing the late dark blue butterfly as an endangered species or threatened species under the Act is not warranted. Furthermore, we did not find any evidence of a concentration of threats at a biologically meaningful scale in any portion of either the early dark blue butterfly's range or the late dark blue butterfly's range. A detailed discussion of the basis for this finding can be found in the species assessment form for the early and late dark blue butterflies and other supporting documents (see **ADDRESSES**, above).

Southern Rubber Boa

Previous Federal Actions

On July 11, 2012, we received a petition from CBD requesting that the Service list 53 amphibians and reptiles in the United States, including the southern rubber boa, as an endangered or threatened species and designate critical habitat for these species under the Act. We published a 90-day finding on 25 species, including the southern rubber boa, in the **Federal Register** on September 18, 2015 (80 FR 56423), in response to the petition. We determined in our 90-day finding that the petition presented substantial scientific or commercial information indicating that listing may be warranted for 23 species, including the southern rubber boa. This document announces the 12-month finding on the July 11, 2012, petition to list the southern rubber boa under the Act.

Summary of Finding

The southern rubber boa is one of six rubber boas of the genus *Charina* that reside within the Boidae family, aptly

named because they have skin that folds in a way that resembles rubber. The southern rubber boa is a stout-bodied snake with a short, blunt tail; measures between 13 and 21 inches (35 and 55 centimeters); and may live over 60 years in the wild. It is historically and currently known exclusively from the higher elevations within the San Bernardino Mountains and San Jacinto Mountains of southern California, in San Bernardino and Riverside Counties, California. Each mountain range is believed to support a single population, as there are no clear separations in the species' distribution within each mountain range. The species is fossorial (burrows), nocturnal, and only infrequently active aboveground.

Southern rubber boa habitat is characterized as montane forest with relatively high humidity, well-developed soil, woody canopy openings, and piles or outcroppings of granitic rock formations. The species uses rock outcroppings, as well as existing rodent burrows, as winter hibernacula—warm areas that allow boas to remain protected underground from predators and winter weather. Deep rock crevices and area beneath large rocks are also used throughout the year for basking at night, or when they are not searching for mates or prey such as juvenile rodents, insects, and lizard eggs. Approximately 88 percent of the species' range, as quantified by our examination of modeled habitat, occurs on public or conserved lands owned and managed by the San Bernardino National Forest, the Bureau of Land Management, the State of California, and local governments and conservancies; thus, the species is protected from large-scale habitat loss. The southern rubber boa's resource needs reflect the species' reliance on moisture; their nocturnal habits; and the importance of shelters for hibernation, gestation, basking under cover, and humidity. Habitat and demographic needs include appropriate humidity, sufficient prey, appropriate gestation sites and shelter, mate availability and adult abundance, and adequate habitat diversity.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the southern rubber boa, and we evaluated all relevant factors under the five listing factors in the Act, including any regulatory mechanisms and conservation measures addressing these threats. We evaluated both San Bernardino and San Jacinto mountain range populations, including, for the purposes of our analysis, evaluating the San Bernardino

Mountains population as consisting of an eastern and a western subpopulation. The primary threats to the southern rubber boa are (1) the loss, degradation, or modification of habitat from drying conditions, and (2) loss of individuals, with the most significant sources of these threats for both individual southern rubber boa losses and species' habitat impacts resulting from changing climate conditions (*i.e.*, drought, increased temperatures), wildfire, and rock pile disturbance from snake collectors and field hobbyists. Other less significant sources of threats that could also result in loss, degradation, or modification of habitat, and loss of individuals, include development/land use change, recreation, infrastructure and forest management, and resource extraction.

After evaluation of impacts from current threats on habitat and demographic needs, we determined that each of the three analysis units (western San Bernardino Mountains subpopulation, eastern San Bernardino Mountains subpopulation, and San Jacinto Mountains population) consist of moderately to highly resilient populations/subpopulations that are likely to be able to withstand normal year-to-year variations in environmental conditions such as temperature changes; periodic disturbances within the normal range of variation such as wildfire; and normal variation in demographic rates such as mortality and fecundity. The best available information indicates the southern rubber boa is also able to withstand catastrophic events within each of the analysis units, and has the ability to adapt to environmental changes, such as changes to climate or habitat conditions. At this time, the best available information (based on our assumptions given significant unknowns surrounding the species and its response to changing habitat conditions) indicates an overall high likelihood that the species will continue to maintain resilient populations in the foreseeable future, particularly in light of significant conservation afforded the species across its range.

Therefore, we find that listing the southern rubber boa as an endangered or threatened species under the Act is not warranted. Furthermore, we did not find any evidence of a concentration of threats at a biologically meaningful scale in any portion of the species' range. A detailed discussion of the basis for this finding can be found in the southern rubber boa species assessment form and other supporting documents (see **ADDRESSES**, above).

Virgin Spinedace

Previous Federal Actions

On November 20, 2012, the Service received a petition from CBD to list the Virgin spinedace as endangered or threatened under the Act. On September 18, 2015, we published a 90-day finding in the **Federal Register** in which we determined that the petition presented substantial scientific or commercial information indicating that listing the Virgin spinedace may be warranted (80 FR 56423). On March 16, 2016, CBD filed a complaint alleging failure to complete a 12-month finding for the species. On August 30, 2016, we entered into a settlement agreement, in which we committed to submitting a 12-month finding to the **Federal Register** by September 30, 2021. This document announces the 12-month finding on the November 20, 2012, petition to list the Virgin spinedace under the Act and fulfills our settlement agreement obligations.

Summary of Finding

The Virgin spinedace is a small freshwater minnow found in the mainstream Virgin River and its tributaries in southwestern Utah (Washington County), northwestern Arizona (Mohave County), and southeastern Nevada (Lincoln County). The species' current distribution is approximately 222 kilometers (138 miles), which is 95 percent of its historical distribution.

The Virgin spinedace is adapted to a highly variable western stream hydrology with intermittent drying. Its resource needs include stream reaches of sufficient length to maintain a population, adequate perennial flow, unimpeded fish passage, suitable habitat (presence of pools, runs, and riffles), suitable water quality, sufficient food base, and absence of predators and competitors. The species is an opportunistic feeder, but primarily feeds on insects.

We have carefully assessed the best scientific and commercial information

available regarding the past, present, and future threats to the Virgin spinedace, and we evaluated all relevant factors under the five listing factors, including any regulatory mechanisms and conservation measures addressing these stressors. The primary stressors affecting the Virgin spinedace's biological status include reduced streamflow, impeded fish passage, habitat destruction, poor water quality, nonnative fish predators/competitors, and climate change. We conducted a population-specific analysis of the environmental conditions that negatively affect individuals or populations of the Virgin spinedace, as well as conservation efforts that ameliorate those stressors. The Virgin spinedace currently exhibits good resiliency, redundancy, and representation. We anticipate maintaining good or fair levels of resiliency, redundancy, and representation in the foreseeable future across a range of future scenarios. There was no concentration of stressors in any significant portion of the species' range sufficient to cause the species to likely become in danger of extinction in the foreseeable future. Our conclusions are supported by the fact that since the Virgin Spinedace Conservation Assessment and Strategy was implemented in 1995, the distribution of the species has increased to within 95 percent of its historical distribution. Implementation of the Virgin Spinedace Conservation Assessment and Strategy is ongoing and involves Federal, State, and local partners.

Therefore, we find that listing the Virgin spinedace as an endangered species or threatened species under the Act is not warranted. Furthermore, we did not find any evidence of a concentration of threats at a biologically meaningful scale in any portion of the species' range. A detailed discussion of the basis for this finding can be found in the Virgin spinedace species assessment form and other supporting documents (see **ADDRESSES**, above).

New Information

We request that you submit any new information concerning the taxonomy of, biology of, ecology of, status of, or stressors to Amargosa tryonia, Ash Meadows pebblesnail, boat-shaped bugseed, Burrington jumping-slug, crystal springsnail, Dalles sideband, distal-gland springsnail, early dark blue butterfly, Fairbanks springsnail, late dark blue butterfly, median-gland springsnail, minute tryonia, Point of Rocks tryonia, southern rubber boa, southwest Nevada pyrg, sportinggoods tryonia, or Virgin spinedace to the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**, whenever it becomes available. New information will help us monitor these species and make appropriate decisions about their conservation and status. We encourage local agencies and stakeholders to continue cooperative monitoring and conservation efforts.

References Cited

A list of the references cited in this petition finding is available in the relevant species assessment form, which is available on the internet at <http://www.regulations.gov> in the appropriate docket (see **ADDRESSES**, above) and upon request from the appropriate person (see **FOR FURTHER INFORMATION CONTACT**, above).

Authors

The primary authors of this document are the staff members of the Species Assessment Team, Ecological Services Program.

Authority

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Martha Williams,

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

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Notices

Federal Register

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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.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Adoption of Recommendation

AGENCY: Administrative Conference of the United States.

ACTION: Notice.

SUMMARY: The Assembly of the Administrative Conference of the United States unanimously adopted Recommendation 2021–5, *Clarifying Access to Judicial Review of Agency Action*, during its 75th Plenary Session.

FOR FURTHER INFORMATION CONTACT: Mark Thomson, Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW, Washington, DC 20036; Telephone 202–480–2080.

SUPPLEMENTARY INFORMATION: The Administrative Conference Act, 5 U.S.C. 591–596, established the Administrative Conference of the United States. The Conference studies the efficiency, adequacy, and fairness of the administrative procedures used by Federal agencies and makes recommendations to agencies, the President, Congress, and the Judicial Conference of the United States for procedural improvements (5 U.S.C. 594(1)). For further information about the Conference and its activities, see www.acus.gov.

The Assembly of the Conference met during its 74th Plenary Session on June 17, 2021, to consider five proposed recommendations. One of them, *Clarifying Statutory Access to Judicial Review of Agency Action*, was remanded to the Conference's Committee on Judicial Review for further consideration of technical issues relating to rulemakings with post-promulgation comment periods. The original proposed recommendation was subsequently amended during a July 22, 2021, meeting of the Committee on Judicial Review, and the committee-amended proposal was unanimously

adopted via electronic vote at the 75th Plenary Session, which was conducted from 9 a.m. on September 13, 2021, until noon on September 17, 2021.

Recommendation 2021–5, *Clarifying Access to Judicial Review of Agency Action*. This recommendation urges Congress to enact a cross-cutting statute that addresses certain recurring technical problems in statutory provisions governing judicial review of agency action that may cause unfairness, inefficiency, or unnecessary litigation. It also offers drafting principles for Congress when it writes new or amends existing judicial review statutes. It draws in large part on ACUS's forthcoming *Sourcebook of Federal Judicial Review Statutes*, which analyzes the provisions in the U.S. Code governing judicial review of agency action.

The Conference based this recommendation on research reports and prior history that are posted at: <https://www.acus.gov/meetings-and-events/event/75th-plenary-session>.

Authority: 5 U.S.C. 595.

Dated: September 21, 2021.

Shawne C. McGibbon,
General Counsel.

Appendix—Recommendation of the Administrative Conference of the United States

Administrative Conference Recommendation 2021–5 Clarifying Access to Judicial Review of Agency Action

Adopted September 17, 2021

Judicial review of federal administrative action is governed by numerous statutes, including two general statutes, the Administrative Procedure Act (APA)¹ and the Hobbs Act,² and hundreds of agency-specific statutes. Judicial review is also governed by judicially developed doctrines.³ The APA's judicial review provisions govern judicial review of agency action generally and provide default rules that apply in the absence of any more specifically applicable rules. Agency-specific statutes (referred to herein as “specific judicial review statutes”) govern judicial review of actions of particular agencies (often, of particular actions of particular agencies) and may provide specifically applicable rules that displace the general provisions of the APA.⁴ Certain

procedural aspects of judicial review are governed by federal court rules that specify how to file a petition for review, the content of the record on review, and other matters.⁵

The Administrative Conference of the United States undertook an initiative to identify and review all statutory provisions in the *United States Code* governing judicial review of federal agency rules and adjudicative orders.⁶ In the course of this initiative, the Conference observed various ways in which some of these statutes create unnecessary obstacles to judicial review or overly complicate the process of judicial review. The Conference recommends eliminating these obstacles and complications in order to promote efficiency and fairness and to reduce unnecessary litigation.⁷

This Recommendation is divided into two sections. The first section (Paragraphs 1–3) recommends a set of drafting principles for Congress when it writes or amends specific judicial review statutes. The second section (Paragraphs 4 and 5) recommends the preparation and passage of a general judicial review statute (referred to below as “the general statute”) that would cure problems in existing judicial review statutes. The Conference's Office of the Chairman has announced that it will prepare and submit to Congress a proposed statute for consideration that would provide for the statutory changes in Paragraph 4. The specific topics covered in the Recommendation are described below.

chapter 7 [of the APA] . . . except to the extent that it does so expressly”).

⁵ See Fed. R. App. P. 15–20.

⁶ See Jonathan R. Siegel, Admin. Conf. of the U.S., *Sourcebook of Federal Judicial Review Statutes* (draft May 28, 2021).

⁷ This Recommendation is not intended to address all issues related to access to judicial review. For example, it does not address the time of accrual of a right of action under the general statute of limitations in 28 U.S.C. 2401(a) (see, e.g., *Wind River Mining Corp. v. United States*, 946 F.2d 710 (9th Cir. 1991)); the extent to which judicial review remains available after the expiration of a time period specified in a special statute authorizing pre-enforcement review of agency rules (see, e.g., *PDR Network, LLC v. Carlton & Harris Chiropractic, Inc.*, 139 S. Ct. 2051 (2019)); the application of judge-made issue-exhaustion requirements in curtailling judicial review (see, e.g., *Carr v. Saul*, 141 S. Ct. 1352 (2021)); or whether Congress should specify where judicial review should be sought with regard to agency actions that are not currently the subject of any specific judicial review statute (see 5 U.S.C. 703 (providing that review of such actions may be sought using “any applicable form of legal action . . . in a court of competent jurisdiction”). The Conference has addressed some of these issues in past recommendations. See, e.g., Admin. Conf. of the U.S., Recommendation 82–7, *Judicial Review of Rules in Enforcement Proceedings*, 47 FR 58208 (Dec. 30, 1982); Admin. Conf. of the U.S., Recommendation 75–3, *The Choice of Forum for Judicial Review of Administrative Action*, 40 FR 27926 (July 2, 1975).

¹ 5 U.S.C. 701–06.

² 28 U.S.C. 2341–51.

³ See generally John F. Duffy, *Administrative Common Law in Judicial Review*, 77 Tex. L. Rev. 113 (1998).

⁴ See 5 U.S.C. 559 (providing that a “[s]ubsequent statute may not be held to supersede or modify . . .

Specifying the Time Within Which To Seek Review

Judicial review statutes typically specify the time within which a party may seek judicial review. The Conference's review revealed two problems that some such statutes cause. First, some specific judicial review statutes specify the time limit using an unusual formulation that results in a time period one day shorter than might be expected. In cases involving these statutes, some parties have lost their right to review because they sought review one day late. Such denials of review serve no substantial policy interest.⁸ Accordingly, Paragraph 1 provides that Congress, when specifying the time within which to seek judicial review of agency action, should use one of the usual forms of words and avoid the unusual forms.⁹ Paragraph 4(a) provides that Congress should include in the recommended general judicial review statute a provision that would add one day to the review period whenever a specific judicial review statute uses one of the unusual forms, thus saving certain cases from dismissal.

The other problem relating to time limits is that some specific judicial review statutes do not clearly identify the event that starts the time within which to seek review. In particular, some specific judicial review statutes provide that the time for seeking review of an agency rule begins when the rule is "issued" or "prescribed," which has led to litigation about exactly what event constitutes the "issu[ance]" of a rule.¹⁰ Paragraph 2 provides as a general matter that Congress should clearly specify what event starts the time for seeking review of agency action. Where an agency promulgates, amends, or repeals a rule after opportunity for participation by interested persons, Paragraph 2 also provides that, in drafting specific judicial review statutes providing for review of an agency rule, Congress should provide that the time for review runs from the rule's publication in the **Federal Register**, where the rule is published in the **Federal Register**.¹¹ This Recommendation does not

address situations in which rules do not have to be published in the **Federal Register**. Paragraph 4(b) provides that Congress should include in the general statute a provision that whenever a time period for seeking judicial review begins upon the issuance of a rule and the rule is published in the **Federal Register**, the time starts when the rule is published in the **Federal Register**.¹²

Specifying the Name and Content of the Document by Which Review Is Sought

When review is to be sought in a court of appeals, most specific judicial review statutes provide that review should be sought by filing either a "petition for review" or a "notice of appeal." The term "petition for review" is more appropriate, as the term "appeal" suggests an appellate court's review of a decision by a lower court.¹³ Paragraph 3 therefore provides that specific judicial review statutes should direct parties to seek review in a court of appeals by filing a petition for review. Problems sometimes arise when a party incorrectly titles the document. In most such cases, the reviewing court treats the incorrect form as the correct one, but occasional decisions refuse to save a party who has given the document the wrong name. Parties should not lose their right to review by filing an incorrectly styled document.¹⁴ Paragraph 4(c) proposes to solve this problem consistent with Paragraph 3's preference for "petitions for review" in courts of appeals.

Paragraph 3 also provides that when review is to be sought in district court, Congress should provide that it be initiated by filing a complaint. District court litigators are accustomed to initiating proceedings with a complaint, and courts are also accustomed to this terminology because the Federal Rules of Civil Procedure contemplate the initiation of an action with the filing of a complaint.¹⁵ Statutes calling for review to be initiated in district court by filing some other document, such as a petition for review or notice of appeal, might be confusing. Paragraph 4(d) proposes a cure for this problem that is consistent with the Paragraph 3's preference for "complaints" in district courts.

Most specific judicial review statutes do not prescribe the content of the document used to initiate review. This salutary practice allows the content of the document to be determined by rules of court, such as Federal Rule of Appellate Procedure 15, which contains only minimal requirements. A few unusual specific judicial review statutes prescribe the content of the petition for review in more detail. These requirements

final, interim final, temporary, or otherwise) notwithstanding the agency's maintaining a period for objections or comments to the rule after its publication. *See, e.g., Milice v. Consumer Prods. Safety Comm'n*, 2 F.4th 994 (D.C. Cir. 2021).

¹² If the relevant judicial review statute is silent with regard to computing or extending the time within which to seek review, the Federal Rules of Civil Procedure and the Federal Rules of Appellate Procedure apply. *See* Fed. R. Civ. P. 6; Fed. R. App. P. 26.

¹³ Siegel, *supra* note 6, at 38–40; *see also Garland v. Dai*, 141 S. Ct. 1669 (2021).

¹⁴ Siegel, *supra* note 6, at 38–40.

¹⁵ Fed. R. Civ. P. 3.

unnecessarily complicate judicial review.¹⁶ Paragraph 3 reminds Congress that specific judicial review statutes need not specify the required content of a petition for review and that Congress may allow the content to be governed by the applicable rules of court. Paragraph 4(e) provides that Congress should include in the general statute a provision generally allowing documents initiating judicial review to comply either with an applicable specific judicial review statute or an applicable rule of court.

Jurisdiction To Hear the Case

The Conference's review uncovered another potential difficulty: Some specific judicial review statutes provide that parties should seek review of agency action in federal courts of appeals but do not specify that these courts will have jurisdiction to hear the resulting cases. In such a case, a court of appeals might question whether it has jurisdiction to consider the petition for review.¹⁷ Accordingly, Paragraph 4(f) provides that Congress should include in the general statute a provision that whenever a specific judicial review statute authorizes a party to seek judicial review of agency action in a specified court, the court will have jurisdiction to consider the resulting case.

Simultaneous Service Requirements

Another potential problem is that some specific judicial review statutes provide that the party seeking judicial review of agency action must transmit the document initiating review to the agency "simultaneously" with filing the document. Such a provision could cause a court to question what should happen if a party seeking review serves the document initiating review on the agency, but not "simultaneously" with filing the document. Although the Conference's review has found no cases dismissed due to such circumstances, the Conference is concerned that a court might read the statutory text as requiring it to dismiss a petition for review based on the lack of simultaneous service.¹⁸ Paragraph 4(g) therefore provides that whenever a specific judicial review statute requires a party seeking judicial review to serve a copy of the document initiating review on the agency involved "simultaneously" with filing it, the service requirement is satisfied if the document is served on the agency within the number of days specified in the recommended general statute.

Race to the Courthouse, Revisited

The Conference's Recommendation 80–5 addressed the "race to the courthouse" problem that arises when multiple parties seek judicial review of the same agency action in different circuits.¹⁹ In accordance with that recommendation, Congress provided by statute that in such cases a lottery will determine which circuit will review the agency's action. The statute,

¹⁶ Siegel, *supra* note 6, at 40–41.

¹⁷ *Id.* at 35–37.

¹⁸ *Id.* at 41–45.

¹⁹ Admin. Conf. of the U.S., Recommendation 80–5, *Eliminating or Simplifying the "Race to the Courthouse" in Appeals from Agency Action*, 45 FR 84954 (Dec. 24, 1980).

⁸ Siegel, *supra* note 6, at 26–30.

⁹ The recommended forms conform to those recommended by the drafting manuals of each house of Congress. *See* U.S. House of Representatives, House Legislative Counsel's Manual on Drafting Style 57 (1995); U.S. Senate, Office of the Legislative Counsel, Legislative Drafting Manual 81–82 (1997).

¹⁰ Siegel, *supra* note 6, at 31–32.

¹¹ This Recommendation addresses judicial review of rules that are issued through a process in which the agency solicits comments and then publishes a rule after consideration of those comments. This Recommendation does not address situations, such as direct final rulemaking, interim-final rulemaking, and temporary rulemaking, in which an agency publishes a rule in the **Federal Register** but invites post-promulgation comments or objections, which may raise unique issues regarding statutes of limitations in some circumstances. *See* Admin. Conf. of the U.S., Recommendation 95–4, *Procedures for Noncontroversial and Expedited Rulemaking*, 60 FR 43110 (Aug. 18, 1995). Those situations can present problems of determining the event date for purposes of judicial review of the rule. Parties should be aware that statutes of limitations may be construed to begin to run upon publication of any rule (whether styled as a direct

however, provides that the lottery system applies only when an agency receives multiple petitions for review “from the persons instituting the proceedings.”²⁰ This provision has been held not to apply to petitions for review forwarded to an agency by a court clerk, as some specific judicial review statutes require. Parties invoking judicial review under such specific judicial review statutes should be entitled to the benefit of the lottery system.²¹ Paragraph 4(h) provides that Congress should amend the “race to the courthouse” statute appropriately.

Recommendation

Recommendations to Congress When Drafting Judicial Review Provisions

1. When specifying the time within which a party may seek judicial review of agency action, Congress should provide that a party may seek review “within” or “not later than” a specified number of days after an agency action. Congress should avoid providing that a party may seek review “prior to” or “before” the day that is a specified number of days after an agency action, or “within” or “before the expiration of” a period of a specified number of days beginning on the date of an agency’s action. Examples of the recommended forms are:

a. “A party seeking judicial review may file a petition for review within 30 days after” the agency’s action.

b. “A party seeking judicial review may file a petition for review not later than 30 days after” the agency’s action.

Examples of the forms to be avoided are:

c. “A party seeking judicial review may file a petition for review prior to [or “before”] the 30th day after” the agency’s action.

d. “A party seeking judicial review may file a petition for review within [or “before the expiration of”] the 30-day period beginning on the date of” the agency’s action.

2. Congress should clearly specify what event starts the time for seeking review. Where the event is the promulgation, amendment, or repeal of a rule by an agency following the opportunity for participation by interested persons, Congress should provide that the event date is the date of the publication of the final rule in the **Federal Register**, where the rule is so published.

3. When drafting a statute providing for review in a court of appeals, Congress should provide that review should be initiated by filing a petition for review. When drafting a statute providing for review in a district court, Congress should provide that review should be initiated by filing a complaint. With regard to either kind of statute, Congress should be aware that it need not specify the required content of the document initiating judicial proceedings because that matter would be governed by the applicable court rules.

General Judicial Review Statute

4. Congress should enact a new general judicial review statute that includes these provisions:

a. Whenever a specific judicial review statute provides that a party may seek judicial review of an agency’s action “prior to” or “before” the day that is a specified number of days after an agency’s action, or “within” or “before the expiration of” a period of a specific number of days beginning on the date of an agency’s action, review may also be sought exactly that number of days after the agency’s action.

b. Whenever a specific judicial review statute provides that the event that starts the time for seeking judicial review is the promulgation, amendment, or repeal of a rule by an agency following the opportunity for participation by interested persons, the event date shall be the date of the publication of the final rule in the **Federal Register**.

c. Statutes authorizing judicial review in a court of appeals by the filing of a notice of appeal will be construed as authorizing judicial review by the filing of a petition for review, and whenever a party seeking judicial review in a court of appeals styles the document initiating review as a notice of appeal, the court will treat that document as a petition for review.

d. Statutes authorizing judicial review in a district court by the filing of a notice of appeal, petition for review, or other petition will be construed as authorizing judicial review by the filing of a complaint, and whenever a party seeking judicial review in a district court styles the document initiating review as a notice of appeal, petition for review, or other petition, the court will treat that document as a complaint.

e. Whenever a specific judicial review statute specifies the required content of a document that initiates judicial review, a party may initiate review with a document that complies with the requirements of that statute or a document that complies with the applicable rules of court.

f. Whenever a specific judicial review statute provides that a party may seek judicial review of an agency action in a specified federal court, the specified federal court will have jurisdiction to hear the resulting case.

g. Whenever a specific judicial review statute requires that a party seeking review serve the document initiating review on the agency that took the action of which review is sought “simultaneously” with filing the document, this requirement is satisfied if the document is served on the agency within a reasonable but specific number of days, such as seven or fourteen days either before or after filing.

h. Congress should amend 28 U.S.C. 2112(a)(1) by striking the phrase “, from the persons instituting the proceedings, the” and inserting “a” in its place, in both places where the phrase occurs.

5. The Conference’s Office of the Chairman should prepare and submit to Congress a proposed general judicial review statute for consideration that would provide for the statutory changes in Paragraph 4.

[FR Doc. 2021–20833 Filed 9–24–21; 8:45 am]

BILLING CODE 6110–01–P

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Request for Public Comment

AGENCY: United States Agency for International Development (USAID).

SUMMARY: The United States Agency for International Development (USAID) seeks Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, USAID requests public comment on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: Send comments on or before November 26, 2021.

ADDRESSES: You may submit comments by any of the following methods:

1. *Email:* jshahan@usaid.gov.

2. *Web:* Through the Federal eRulemaking Portal at www.regulations.gov by following the instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT:

Kristen Rancourt, USAID Bureau for Management, Office of Management, Policy, Budget and Performance, Policy Division (M/MPBP/POL), telephone (202) 921–5119, or via email at krancourt@usaid.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Exchange Visitor (EV) Visa Compliance program is a central management function that enables USAID to comply with statutory and regulatory requirements associated with sponsoring foreign nationals who enter the United States (U.S.) on a J–1 visa. This function aligns with the U.S. National Security Strategy, and the Foreign Assistance Act of 1961 authorizing the U.S. government to conduct educational and cultural exchanges for the purpose of strengthening the capacity and commitment of host-country nationals to address development challenges in their respective countries. These educational and cultural exchanges are defined by section 102 of the Mutual Educational and Cultural Exchange Act of 1961 (the “Act”), 22 U.S.C. 2452. The regulations set forth in the Code of Federal Regulations (CFR) Title 22, Part 62 “Exchange Visitor Program” implement the Act, and appoints USAID as a designated sponsoring organization. Program sponsors are responsible for selecting, supporting and monitoring participants during their entire program stay.

²⁰ 28 U.S.C. 2112(a)(1).

²¹ Siegel, *supra* note 6, at 42–45.

Section 112 of the Act, as amended, codified the establishment of the Interagency Working Group (IAWG) on U.S. Government-Sponsored International Exchanges and Training, and mandated the IAWG with managing a “coordinated strategy for all U.S. Government-sponsored international exchange and training programs,” with a primary purpose and responsibility “to collect, analyze, and report data provided by all U.S. Government departments and agencies conducting international exchanges and training programs.” As a statutory member of the IAWG, USAID participates in the annual mandated request for data reporting on USAID international exchanges and training programs and participants.

The Training and Exchanges Automated Management System (TEAMS) is USAID’s official data management system and the entry point for data for U.S. exchange visitor programs. TEAMS incorporates processes to manage and support EV’s who will come to the U.S. on a USAID J–1 visa. TEAMS manages data by interfacing with the Department of Homeland Security’s (DHS) Student and Exchange Visitor Information System (SEVIS), the system that DHS uses to maintain and monitor participants in U.S. programs. All EV’s must be registered in SEVIS. USAID utilizes SEVIS to report on EV programs, and to issue Certificates of Eligibility for Exchange Visitor Status (Form DS–2019). The Automated Directive System (ADS) Chapter 252—Visa Compliance for Exchange Visitors, requires Agency operating units (OUs) or their Implementing Partners, in accordance with their awards, to enter data into TEAMS relevant to U.S. visits by sponsored foreign nationals who are recipients of USAID development assistance. TEAMS replaces the Training Results and Information Network (TraiNet) and Visa Compliance System (VCS). TEAMS combines the functionality of TraiNet and VCS into one system.

The Bureau for Management, Office of Management Policy, Budget and Performance (M/MPBP) relies on TEAMS data for the following uses: (1) EV program management; (2) batching USAID data to SEVIS; and, (3) annual mandated reporting to IAWG. USAID OUs use TEAMS data of U.S.-based EVs, and in-country and third-country based training participants, for internal reporting and portfolio management.

II. Method of Collection

Electronic.

III. Data

Title of Information Collection: Training and Exchanges Automated Management System (TEAMS).

Type of Review: New Information Collection.

OMB Number: Not assigned.

Affected Public who will be asked or required to respond: Exchange Visitor’s as defined in ADS Chapter 252—Visa Compliance for Exchange Visitors.

Estimated Total Number of Respondents per Year: Approximately 1,500–2,000 annually based on current year estimates.

Estimated Total Annual Burden: 375–500 hours (1,500–2000 participants × 15 minutes per participant).

IV. Request for Comments

All comments must be in writing and submitted through the methods specified in the **ADDRESSES** section above. All submissions must include the information collection title. Please include your name, title, organization, postal address telephone number, and email address in the text of the message. Please note that comments submitted in response to this Notice are public record. We recommend that you do not submit detailed personal information, confidential business information, or any information that is otherwise protected from disclosure by statute.

USAID will only address comments that explain why the proposed collection would be inappropriate, ineffective, or unacceptable without a change. Comments that are insubstantial or outside the scope of the notice of request for public comment may not be considered.

Susan C. Radford,

Management and Program Analyst, Bureau for Management, Office of Management Policy, Budget, and Performance, U.S. Agency for International Development.

[FR Doc. 2021–20900 Filed 9–24–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Intent To Establish an Equity Commission and Solicitation of Nominations for Membership on the Equity Commission Advisory Committee and Equity Commission Subcommittee on Agriculture

AGENCY: United States Department of Agriculture (USDA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA), the United States Department

of Agriculture announces its intent to establish an Equity Commission (EC) including a Subcommittee on Agriculture. The EC will advise the Secretary of Agriculture by facilitating identification of critical USDA programs, policies, systems, structures, and practices that contribute to barriers to inclusion or access, systemic discrimination, or exacerbate or perpetuate racial, economic, health and social disparities. The EC will be governed by the provisions of FACA. Concurrent to creation of the Equity Commission, a Subcommittee on Agriculture will be formed that will be charged with providing recommendations on issues of concern related to agriculture to optimize USDA programs, dismantle structural inequities and systemic discrimination, and promote social justice particularly for historically underserved and diverse communities served by USDA. This notice also solicits nominations for membership on the EC and the EC’s Subcommittee on Agriculture.

DATES: We will consider nominations that are submitted via email or postmarked by October 27, 2021.

ADDRESSES: Please submit nominations to Dr. Dewayne L. Goldmon, USDA Senior Advisor for Racial Equity, Office of the Secretary, Department of Agriculture, 1400 Independence Avenue SW, Room 6006–S, Washington, DC 20250; or send by email to: EquityCommission@usda.gov. A Federal Official of USDA will acknowledge receipt of nominations.

FOR FURTHER INFORMATION CONTACT: Dewayne L. Goldmon, Ph.D.; telephone: (202) 997–2100; email: dewayne.goldmon@usda.gov.

SUPPLEMENTARY INFORMATION: Section 1006(a)(3) of the American Rescue Plan Act of 2021 directs the Secretary of the United States Department of Agriculture to create an Equity Commission to advise the Agency in “address[ing] historical discrimination and disparities in the agriculture sector,” which includes “fund[ing] one or more equity commissions to address racial equity issues within USDA and its programs.” Public Law 117–2.

EC and Subcommittee on Agriculture Scope and Purpose

The purpose of the EC is to advise the Secretary of Agriculture by identifying USDA programs, policies, systems, structures, and practices that contribute to barriers to inclusion or access, systemic discrimination, or exacerbate or perpetuate racial, economic, health and social disparities.

The scope of duties of the EC is advisory and extends only to the submission of advice and recommendations to the Secretary, which shall be non-binding. The EC will make no determination of fact or policy.

The EC will deliver an interim report focused on characterizing the problems and barriers to accessing USDA programs and services and provide actionable recommendations on reducing these barriers that underserved individuals, organizations, businesses, or communities may face accessing the information, resources, programs, and services USDA offers, no later than 12 months after inception. A final report on the same topic shall be generated within a two-year timeframe.

The EC is expected to begin meeting during the Winter of 2021/2022 and to meet up to four times per year (either virtually or in person, or as deemed necessary by the Secretary of Agriculture). Pursuant to FACA, all EC meetings will be open to the public.

The Subcommittee on Agriculture will be formed concurrently and be focused on providing recommendations on issues of concern related to agriculture. The subcommittee will meet as deemed necessary by the subcommittee chairperson and may meet through teleconference or by computer-based conferencing. The EC and subcommittee may invite subject matter experts to present information for consideration. The subcommittee meetings will not be announced in the **Federal Register**. All data and records available to the full EC are expected to be available to the public when the full EC reviews and approves the work of the subcommittee.

EC and Subcommittee on Agriculture Overview and Membership

The criteria for consideration for membership on the EC and Subcommittee on Agriculture include diversity in demographics, regions of the country, background, and in experience and expertise. The EC must adhere to equal opportunity practices consistent with USDA policy. The EC and subcommittee will require substantial representation from those whose mission is to serve or advocate for underserved communities, minorities, women, individuals with disabilities, individuals with limited English proficiency, rural communities, and LGBTQI+ communities. Other perspectives to capture include those from the small business community, higher education institutions, farmworker groups, and members of the American population and communities

who bring their personal experiences to the discussion.

The EC shall be composed of 15 members appointed by the Secretary of Agriculture for a two-year term and may be reappointed for up to two additional terms, and shall include:

- 2 representatives from community-based organizations that represent underserved communities;
- 2 representatives with expertise in policy design and/or evaluation;
- 2 representatives with expertise in organizational development, design thinking, and/or change management;
- 1 representative with expertise in communications/public relations;
- 1 representative with expertise in civil rights;
- 1 representative with expertise in organizational diversity, equity, and inclusion;
- 1 economist with knowledge of social policy and economic disparities;
- 1 historian;
- 1 legal expert; and
- 3 such other persons representing a broad spectrum of related interests as the Secretary considers appropriate.

The Secretary and Deputy Secretary will designate a Co-Chair to serve along with the Deputy Secretary, serving one (1) year from the date of appointment to the Equity Commission; their role as Co-Chair may be renewed. The Co-Chair will be an individual who is recognized for their ability to lead in a fair and focused manner.

The EC members will be reimbursed for travel expenses, including per diem instead of subsistence, authorized by 5 U.S.C. 5703, in the same manner as a person employed intermittently in the Government service.

The EC's Subcommittee on Agriculture will be comprised of 15 members who have expertise in agriculture, federal farm, conservation, and extension programs. Two members of the Subcommittee on Agriculture will be members of the EC. The majority of the subcommittee members should be familiar with USDA and reflect the diversity of agriculture in geography, size, scale, and type of production. The majority of subcommittee members should represent historically underserved populations or communities and shall include:

- 3 farmers or ranchers;
- 2 university personnel with research and/or extension expertise from minority serving institutions;
- 2 individuals from community based organizations;
- 1 individual from the agricultural industry;
- 1 individual representing farmworker groups;

- 1 individual with civil rights and equity expertise;
- 3 individuals selected at the discretion of the Secretary; and
- 2 members of the EC (as explained above).

The Subcommittee on Agriculture will report back to the parent committee (EC), and must not provide advice or work products directly to the agency.

Member Nominations

Any interested person or organization may nominate qualified individuals for membership. Interested candidates may nominate themselves. Individuals who wish to be considered for membership on the EC and/or the Subcommittee on Agriculture must submit a nomination with information, including a background disclosure form (Form AD-755). Nominations should be typed and include the following:

1. A brief summary, no more than two pages, explaining the nominee's qualifications to serve on the EC or subcommittee and addressing the membership composition and criteria described above.
2. A resume providing the nominee's background, experience, and educational qualifications.
3. A completed background disclosure form (Form AD-755) signed by the nominee https://www.ocio.usda.gov/sites/default/files/docs/2012/AD-755-Approved_Master-exp-3.31.22_508.pdf.
4. Any recent publications by the nominee relative to organizational change management, diversity equity and inclusion, reducing barriers to accessing public programs and services, addressing historical discrimination and disparities or other related works that would make evident why an individual's experience, expertise and perspective would add value to the Equity Commission or Agriculture Subcommittee (if appropriate).
5. Letters of endorsement (optional).

Nomination for the EC and subcommittee membership is open to the public, including minorities, LGBTQI+ individuals, women, and persons with disabilities in areas designated within the United States, Caribbean Area (Puerto Rico and the U.S. Virgin Islands), and the Pacific Basin Area (Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands).

All candidates should have a shared commitment to ensuring USDA is a diverse, equitable, inclusive, accessible organization that upholds its commitment to civil rights and effectively advances racial justice and equity. Please send typed nominations to:

Office of the Secretary, Attn: Dewayne L. Goldmon, Ph.D., 1400 Independence Avenue SW, Room 6006-S, Washington, DC 20250; telephone: (202) 997-2100, email: EquityCommission@usda.gov

A Federal Official of USDA will acknowledge receipt of nominations.

Ethics Statement

To maintain the highest levels of honesty, integrity and ethical conduct, no Committee or subcommittee member shall participate in any "specific party matters" (*i.e.*, matters are narrowly focused and typically involve specific transactions between identified parties) such as a lease, license, permit, contract, claim, grant, agreement, or related litigation with the Department in which the member has a direct financial interest. This includes the requirement for Committee or Subcommittee members to immediately disclose to the DFO (for discussion with USDA's Office of Ethics) any specific party matter in which the member's immediate family, relatives, business partners or employer would be directly seeking to financially benefit from the Committee's recommendations.

All members will receive ethics training to identify and avoid any actions that would cause the public to question the integrity of the Committee's advice and recommendations. Members who are appointed as "Representatives" are not subject to Federal ethics laws because such appointment allows them to represent the point(s) of view of a particular group, business sector or segment of the public.

Members appointed as "Special Government Employees" (SGEs) are considered intermittent Federal employees and are subject to Federal ethics laws. SGE's are appointed due to their personal knowledge, academic scholarship, background or expertise. No SGE may participate in any activity in which the member has a prohibited financial interest. Appointees who are SGEs are required to complete and submit a Confidential Financial Disclosure Report (OGE-450 form) via the FDonline e-filing database system. Upon request USDA will assist SGEs in preparing these financial reports. To ensure the highest level of compliance with applicable ethical standards USDA will provide ethics training to SGEs on an annual basis. The provisions of these paragraphs are not meant to exhaustively cover all Federal ethics laws and do not affect any other statutory or regulatory obligations to which advisory committee members are subject.

Equal Opportunity Statement

To ensure that recommendations of the EC take into account the needs of underserved and diverse communities served by the USDA, membership will include, to the extent practicable, individuals representing minorities, women, and persons with disabilities. USDA prohibits discrimination in all of its programs and activities based on race, sex, color, national origin, gender, religion, age, sexual orientation, or disability. Additionally, discrimination based on political beliefs and marital status or family status is also prohibited by statutes enforced by USDA (not all prohibited bases apply to all programs). Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's Technology and Accessible Resources Give Employment Today Center at (202) 720-2600 (voice and TDD). USDA is an equal opportunity provider and employer.

Dated: September 21, 2021.

Cikena Reid,

Committee Management Officer, USDA.

[FR Doc. 2021-20840 Filed 9-24-21; 8:45 am]

BILLING CODE 3410-01-P

DEPARTMENT OF AGRICULTURE

Forest Service

Kisatchie Resource Advisory Committee

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of meeting.

SUMMARY: The Kisatchie Resource Advisory Committee (RAC) will hold a virtual meeting by phone/video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information and virtual meeting information can be found at the following website: <https://www.fs.usda.gov/detailfull/kisatchie/home/?cid=fseprd518681&width=full>.

DATES: The meeting will be held on October 14, 2021 at 3:00 p.m. to 7:00 p.m., Central Daylight Time.

All RAC meetings are subject to cancellation. For status of the meeting

prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held virtually via telephone and video conference. The public may access the virtual meeting details and invitation at the following website: <https://www.fs.usda.gov/detailfull/kisatchie/home/?cid=fseprd518681&width=full>.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received upon request.

FOR FURTHER INFORMATION CONTACT: Lisa Lewis, Designated Federal Officer (DFO), by phone at 318-473-7102 or email at lisa.w.lewis@usda.gov or Jim Caldwell, RAC Coordinator, at 337-353-4668 or email at james.caldwell@usda.gov.

Individuals who use telecommunication devices for the deaf/hard-of-hearing (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Hear from Title II project proponents and discuss project proposals;
2. Make funding recommendations on Title II projects;
3. Select a Chairperson for the committee;
4. Approve meeting minutes; and
5. Set a date for the next meeting.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should make a request in writing by October 8, 2021, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Stacy Blomquist, Kisatchie National Forest, 2500 Shreveport Hwy., Pineville, LA 71360; or by email to stacy.blomquist@usda.gov.

Meeting Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. For access to proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Dated: September 21, 2021.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2021-20832 Filed 9-24-21; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Flathead Resource Advisory Committee

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of meeting.

SUMMARY: The Flathead Resource Advisory Committee (RAC) will hold two virtual meetings by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act as well as make recommendations on recreation fee proposals for sites on the Flathead National Forest within Flathead County, MT, consistent with the Federal Lands Recreation Enhancement Act. RAC information and virtual meeting information can be found at the following website: <https://www.fs.usda.gov/main/flathead/workingtogether/advisorycommittees>.

DATES: The meetings will be held on October 20 and 21, 2021, both at 4:00 p.m. to 8:00 p.m., Mountain Daylight Time.

All RAC meetings are subject to cancellation. For status of the meetings prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meetings will be held virtually via telephone and/or video conference. The public may join the meetings by dialing 1-636-352-2946 and using access code: 658379992#. Additional information on how to join will be posted at the website listed in the **SUMMARY**.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received upon request.

FOR FURTHER INFORMATION CONTACT:

Heather Seals, RAC Coordinator, by phone at 406-758-5251 or via email at heather.m.seals@usda.gov.

Individuals who use telecommunication devices for the deaf/hard-of-hearing (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The purpose of the meetings are to hear from Title II project proponents and discuss project proposals.

The meetings are open to the public. The agendas will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement at any of the meetings should make a request in writing by October 4, 2021 to be scheduled on the agenda for that particular meeting. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meetings. Written comments and requests for time for oral comments must be sent to Heather Seals, RAC Coordinator, 650 Wolfpack Way, Kalispell, MT 59901 or by email to heather.m.seals@usda.gov or via facsimile to 406-758-5251.

Meeting Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Dated: September 22, 2021.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2021-20870 Filed 9-24-21; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Southwest Idaho Resource Advisory Committee

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of meeting.

SUMMARY: The Southwest Idaho Resource Advisory Committee (RAC) will hold a virtual meeting by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal

Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act as well as make recommendations on recreation fee proposals for sites on the Payette National Forest within Valley and Adams Counties, ID, consistent with the Federal Lands Recreation Enhancement Act. RAC information and virtual meeting information can be found at the following website: <https://www.fs.usda.gov/main/boise/workingtogether/advisorycommittees>.

DATES: The meeting will be held on October 12, 2021 at 2:00 p.m. to 6:00 p.m. Mountain Daylight Time.

All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under *For Further Information Contact*.

ADDRESSES: The meeting will be held virtually via Zoom video conference. Members of the public may join the meeting via the following link: <https://usfs.zoomgov.com/j/1605603337>.

Written comments may be submitted as described under *Supplementary Information*. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received upon request.

FOR FURTHER INFORMATION CONTACT:

Brian Harris, Designated Federal Officer (DFO), by phone at 208-634-6945 or email at brian.d.harris@usda.gov.

Individuals who use telecommunication devices for the deaf/hard-of-hearing (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Present Recreation Fee Program proposals as submitted by the Payette National Forest, and
2. Discuss and make recommendations to the Forest Supervisor regarding the Payette National Forest's Recreation Fee Program proposals.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should make a request in writing by October 4, 2021, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee

staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Brian Harris, 500 North Mission Street, McCall, Idaho 83638 or by email to brian.d.harris@usda.gov.

Meeting Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. For access to proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Dated: September 22, 2021.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2021-20877 Filed 9-24-21; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Lincoln Resource Advisory Committee

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of meeting.

SUMMARY: The Lincoln Resource Advisory Committee (RAC) will hold a virtual meeting by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act as well as make recommendations on recreation fee proposals for sites on the Kootenai National Forest within Lincoln County, MT, consistent with the Federal Lands Recreation Enhancement Act. RAC information and virtual meeting information can be found at the following website: <https://www.fs.usda.gov/main/kootenai/workingtogether/advisorycommittees>.

DATES: The meeting will be held on October 13, 2021 at 1:00 p.m. to 5:00 p.m., Mountain Daylight Time.

All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held virtually via Microsoft Teams for video/phone conference. The public can view

meeting participation details on the website listed above in the **SUMMARY** section.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received upon request.

FOR FURTHER INFORMATION CONTACT:

Chad Benson, Designated Federal Officer (DFO), by phone at 406-293-6211 or email at chadwick.benson@usda.gov or LaRona Rebo, RAC Coordinator, at 406-283-7764 or email at larona.rebo@usda.gov. Individuals who use telecommunication devices for the deaf/hard-of-hearing (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Hear from Title II project proponents and discuss project proposals;
2. Make funding recommendations on Title II projects;
3. Approve meeting minutes; and
4. Schedule the next meeting.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should make a request in writing by September 24, 2021, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to LaRona Rebo, 313474 US Hwy 2, Libby, MT 59923 or by email to larona.rebo@usda.gov.

Meeting Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Dated: September 21, 2021.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2021-20836 Filed 9-24-21; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service (NASS), USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection, the Cost of Pollination Survey. This survey gathers data related to the costs incurred by farmers to improve the pollination of their crops through the use of honey bees and other pollinators.

DATES: Comments on this notice must be received by November 26, 2021 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535-0258, by any of the following methods:

- *Email:* ombofficer@nass.usda.gov.

Include docket number above in the subject line of the message.

- *eFax:* (855) 838-6382.

- *Mail:* Mail any paper, disk, or CD-ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250-2024.

- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250-2024.

FOR FURTHER INFORMATION CONTACT:

Kevin L. Barnes, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720-2707. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at (202) 690-2388 or at ombofficer@nass.usda.gov.

SUPPLEMENTARY INFORMATION:

Title: Cost of Pollination Survey.

OMB Control Number: 0535-0258.

Type of Request: Intent to Seek Approval to Revise and Extend an Information Collection for 3 years.

Abstract: The primary objective of the National Agricultural Statistics Service (NASS) is to prepare and issue state and national estimates of crop and livestock production, prices, and disposition; as

well as economic statistics, environmental statistics related to agriculture, and also to conduct the Census of Agriculture. Pollinators (honey bees, bats, butterflies, hummingbirds, etc.) are vital to the agricultural industry for pollinating numerous food crops for the world's population. Concern for honey bee colony mortality has risen since the introduction of *Varroa* mites in the United States in the late 1980s and the appearance of Colony Collapse Disorder in the past decade.

In June 2014, the Obama Administration issued a Presidential Memorandum directing federal agencies to take steps to protect and restore domestic populations of pollinators. The memorandum established the Pollinator Health Task Force (Task Force), which is co-chaired by the United States Department of Agriculture (USDA) and Environmental Protection Agency (EPA) and includes leaders from 14 executive branch departments, agencies, and offices. The Task Force's plan involved conducting research and collecting data for the following categories: Status & Trends, Habitats, Nutrition, Pesticides, Native Plants, Collections, Genetics, Pathogens, Decision Tools, and Economics. The pollinators have been classified into Honey Bee, Native Bee, Wasp, Moth/Butterfly, Fly, and Vertebrate. The departments that conducted the bulk of the research were the Department of the Interior (DOI), the Environmental Protection Agency (EPA), the National Science Foundation (NSF), the Smithsonian Institute (SI), and the United States Department of Agriculture (USDA).

NASS was given the tasks of collecting economic data related to honey bees and quantifying the number of colonies that were lost or reduced. NASS is approved to conduct the annual Bee and Honey Inquiry (operations with five or more colonies) and the quarterly Colony Loss Survey (operations with five or more colonies) under OMB #0535-0153. In 2019, funding for the Cost of Pollination Survey were cut and the survey was suspended. Under the 2022 Senate Appropriations Bill, funding is provided for the reinstatement of the Cost of Pollination Survey. Provided the Bill is signed into law as written; NASS will resume data collection on this survey in 2022.

NASS will collect economic data from crop farmers who rely on pollinators for their crops (fruits, nuts, vegetables, etc.). Data relating to the targeted crops are collected for the total number of acres that rely on honey bee pollination, the

number of honey bee colonies that were used on those acres, and any cash fees associated with honey bee pollination. Crop Farmers are also asked if beekeepers who were hired to bring their bees to their farm were notified of pesticides used on the target acres, how many acres they were being hired to pollinate, and how much they were being paid to pollinate the targeted crops.

Authority: These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-113) and the Office of Management and Budget regulations at 5 CFR part 1320. This survey is also conducted in accordance with the Confidential Information Protection and Statistical Efficiency Act of 2018, Title III of Public Law 115-435, codified in 44 U.S.C. Ch. 35.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 15 minutes per response. Publicity materials and an instruction sheet for reporting via internet will account for 5 minutes of additional burden per respondent. Respondents who refuse to complete a survey will be allotted 2 minutes of burden per attempt to collect the data.

Once a year, NASS will contact approximately 18,000 crop farmers who rely on honey bees to pollinate their fruit, nut, vegetable, and other crops. NASS will conduct the annual survey using a mail and internet approach. This will be followed up with phone and personal enumeration for non-respondents. NASS will attempt to obtain at least an 80% response rate.

Respondents: Farmers.

Estimated Number of Respondents: 18,000.

Estimated Total Annual Burden on Respondents: With an estimated response rate of approximately 80%, we estimate the burden to be 5,340 hours.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility,

and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological, or other forms of information technology collection methods. All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, September 17, 2021.

Kevin L. Barnes,

Associate Administrator.

[FR Doc. 2021-20856 Filed 9-24-21; 8:45 am]

BILLING CODE 3410-20-P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

[Docket #: RBS-21-BUSINESS-0032]

Notice of Solicitation of Applications for Inviting Applications for the Rural Business Development Grant Programs for Fiscal Year 2022

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: This notice is given to invite applications for grants under the Rural Business Development Grant (RBDG) Program for fiscal year (FY) 2022, subject to the availability of funding. This notice is being issued in order to allow applicants sufficient time to leverage financing, prepare and submit their applications, and give the Agency time to process applications within FY 2022. Successful applications will be selected by the Agency for funding and subsequently awarded to the extent that funding may ultimately be made available through appropriations. An announcement on the website at <https://www.rd.usda.gov/newsroom/notices-solicitation-applications-nosas> will identify the amount available in FY 2022 for RBDG applications. All applicants are responsible for any expenses incurred in developing their applications.

DATES: Complete applications may be submitted in paper or electronic format and must be received by 4:30 p.m. local time on February 28, 2022, in the USDA Rural Development State Office for the State where the Project is located. A list of the USDA Rural Development State Offices can be found at: <https://www.rd.usda.gov/about-rd/state-offices>.

ADDRESSES: This funding announcement will also be announced on www.Grants.gov. Applications must be

submitted to the USDA Rural Development State Office for the State where the Project is located. For Projects involving multiple states, the application must be filed in the Rural Development State Office where the Applicant is located. Applicants are encouraged to contact their respective Rural Development State Office for an email contact to submit an electronic application prior to the submission deadline date. A list of the USDA Rural Development State Office contacts can be found at: <https://www.rd.usda.gov/about-rd/state-offices>.

FOR FURTHER INFORMATION CONTACT: Lisa Sharp at lisa.sharp@usda.gov, or Cindy Mason at cindy.mason@usda.gov, Program Management Division, Rural Business-Cooperative Service, U.S. Department of Agriculture, 1400 Independence Avenue SW, MS 3226, Room 5160-South, Washington, DC 20250-3226, or call (202) 720-1400. For further information on submitting program applications under this notice, please contact the USDA Rural Development State Office in the State where the applicant's headquarters is located. A list of Rural Development State Office contacts is provided at the following link: <https://www.rd.usda.gov/about-rd/state-offices>.

Overview

Solicitation Opportunity Type: Rural Business Development Grant.

Announcement Type: Initial Solicitation Announcement.

Catalog of Federal Domestic

Assistance Number: 10.351.

Dates: The deadline for completed applications to be received in the USDA Rural Development State Office has been established as no later than 4:30 p.m. (local time) on February 28, 2022. A list of the USDA Rural Development State Offices can be found at: <https://www.rd.usda.gov/about-rd/state-offices>.

Set Aside Funding: The Consolidated Appropriations Act, 2021 (Pub. L. 116-260), designated funding for Federally-Recognized Native American Tribes, Rural Empowerment Zone/Enterprise Communities/Rural Economic Area Partnerships, projects in Persistent Poverty Counties (as discussed below), Native American Persistent Poverty areas and for Strategic Economic and Community Development (SECD) projects in FY 2021. Set aside funding may ultimately be made available through appropriations in FY 2022 where continued emphasis is given to financial assistance for projects located in these areas. Eligible applicants for the Native American and Rural Empowerment Zone/Enterprise Communities/Rural Economic Area

Partnership set aside funds, if available, must demonstrate that at least 75 percent of the benefits of an approved grant will assist beneficiaries in the designated areas. Eligible applicants for the Persistent Poverty Counties, Native American Persistent Poverty areas, and the SECD set-aside funds, if available, must demonstrate that 100 percent of the benefits of an approved grant will assist beneficiaries in the designated areas. The completed application deadline for these set aside funds, if available, is consistent with the RBDG application deadline date of February 28, 2022. Applicants for set aside funds must indicate that they are applying for set aside funds and may not submit a duplicate application for regular RBDG funds. If funding for an anticipated set aside program is not appropriated in FY 2022, or if any eligible applications for set aside funding are not funded due to insufficient funds, such applications will be allowed to compete for available FY 2022 regular RBDG funds in the State where the Project is located.

Persistent poverty counties: The Consolidated Appropriations Act, 2021 (Pub. L. 116-260) designated funding for projects in Persistent Poverty Counties. "Persistent Poverty Counties" as defined in Section 736 is "any county that has had 20 percent or more of its population living in poverty over the past 30 years, as measured by the 1990 and 2000 decennial censuses, and 2007-2011 American Community Survey 5-year average, or any territory or possession of the United States". Another provision in Section 736 expands the eligible population in Persistent Poverty Counties to include any county seat of such a Persistent Poverty County that has a population that does not exceed the authorized population limit by more than 10 percent. This provision expands the current 50,000 population limit to 55,000 for only county seats located in Persistent Poverty Counties. Therefore, beneficiaries of technical assistance services located in county seats of Persistent Poverty Counties with populations up to 55,000 (per the 2010 Census) are eligible.

A. Program Description

1. *Purpose of the Program.* The purpose of the program is to promote economic development and job creation projects through the awarding of grant funds to eligible entities. Applications will compete in two separate categories, business opportunity grants and business enterprise grants, for use in funding various business and community projects that serve rural areas.

Business opportunity projects must be in compliance with eligible uses as stated in 7 CFR 4280.417(a)(1) that include the establishment of business support centers or providing funds for job training and leadership development in rural areas. Business opportunity projects must be consistent with any local and area-wide strategic plans for community and economic development, coordinated with other economic development activities in the project area, and consistent with any Rural Development State Strategic Plan.

Business enterprise projects must be in compliance with 7 CFR 4280.417(a)(2) and are used to finance or develop small and emerging businesses in rural areas. Enterprise grant purposes include projects for the acquisition and development of land, access streets and roads, the conversion or modernization of buildings, capitalization of revolving loan funds and the purchase of machinery and equipment for businesses located in a rural area.

The Agency encourages applicants to consider projects that will advance the key priorities below:

- Assisting Rural communities recover economically from the impacts of the COVID-19 pandemic, particularly disadvantaged communities.
- Ensuring all rural residents have equitable access to RD programs and benefits from RD funded projects.
- Reducing climate pollution and increasing resilience to the impacts of climate change through economic support to rural communities.

2. *Statutory and Regulatory Authority.* The RBDG Program is authorized under 7 U.S.C. 1932(c) and implemented by 7 CFR part 4280, subpart E. Assistance provided under the RBDG Program will be made to eligible entities and will be used for funding various business opportunity projects and business enterprise projects, as applicable, that serve Rural Areas.

3. *Definition of Terms.* The definitions applicable to this notice are published at 7 CFR 4280.403.

4. *Application Awards.* Awards under the RBDG Program will be made on a competitive basis using specific selection criteria contained in 7 CFR part 4280, subpart E. The Agency will review, evaluate, and score applications received in response to this notice based on the provisions found in 7 CFR part 4280, subpart E, and as indicated in this notice. The Agency advises all interested parties that the applicant bears the full burden in preparing and submitting an application in response to this notice whether or not funding is

appropriated for this Program in FY 2022.

B. Federal Award Information

Type of Awards: Grants.

Fiscal Year Funds: FY 2022.

Available Funds: Anyone interested in submitting an application for funding under this Program is encouraged to consult the Rural Development Notices of Solicitation of Applications website at <http://www.rd.usda.gov/newsroom/notices-solicitation-applications-nosas>.

Anticipated Award Dates: Set Aside awards, if applicable: May 31, 2022. Regular awards: August 31, 2022.

Performance Period: June 1, 2022, through September 30, 2024.

Renewal or Supplemental Awards: None.

C. Eligibility Information

1. Eligible Applicants.

Grants may be made to a Public Body/ Government Entity, an Indian Tribe, or a Nonprofit entity primarily serving rural areas. In accordance with 7 CFR 4280.416(d), applicants that are not delinquent on any Federal debt or not otherwise disqualified from participation in these Programs are eligible to apply. The Agency will check the System for Award Management (SAM) to determine if the applicant has been debarred or suspended at the time of application and prior to the awarding of grant funds.

2. Dun and Bradstreet Data Universal Numbering System and System for Award Management.

All applicants must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number which can be obtained at no cost via a toll-free request line at (866) 705-5711 or at <http://fedgov.dnb.com/webform> or any subsequent unique entity identifier number. Each applicant applying for loan or grant funds must (i) be registered in the System for Award Management (SAM) before submitting its application and (ii) provide a valid unique entity identifier in its application, unless determined exempt under 2 CFR 25.110. Applicants must maintain an active SAM registration, with current, accurate and complete information, at all times during which it has an active Federal award or an application under consideration by a Federal awarding agency. Applicants must ensure they complete the Financial Assistance General Certifications and Representations in SAM.

The Agency will not make an award until the applicant has complied with all applicable DUNS (unique entity identifier) and SAM requirements. If an applicant has not fully complied with

the requirements by the time the Agency is ready to make an award, the agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

All other restrictions in this notice will apply.

The Agency requires information to make an eligibility determination through applications that must include, but are not limited to, the following:

(a) An original and one copy of SF-424, "Application For Federal Assistance (For Non-construction)" and an original Form RD 400-4, "Assurance Agreement";

(b) Copies of applicant's organizational documents showing the applicant's legal existence and authority to perform the activities under the grant;

(c) A proposed scope of work, including a description of the proposed Project. Grant funds may be used for projects identified in 7 CFR 4280.417(a) as either a business opportunity type grant or a business enterprise type grant. The scope of work must include details of the proposed activities to be accomplished and timeframes for completion of each task, the number of months duration of the Project, and the estimated time it will take from grant approval to beginning of Project implementation. In accordance with 7 CFR 4280.421, a Project must reasonably be expected to be completed within 1 full year after it has begun;

(d) A written narrative that includes, at a minimum, the following items:

(1) An explanation of why the Project is needed, the benefits of the proposed Project, and how the Project meets the eligible grant purposes;

(2) Area to be served, identifying each governmental unit, *i.e.*, town, county, Indian reservation, etc., to be affected by the Project;

(3) Description of how the Project will coordinate Economic Development activities with other Economic Development activities within the Project area;

(4) Business to be assisted, if appropriate, and Economic Development to be accomplished;

(5) An explanation of how the proposed Project will result in newly created, increased, or supported jobs in the area and the number of projected new and supported jobs within the next 3 years;

(6) A description of the applicant's demonstrated capability and experience in providing the proposed Project assistance or similar Economic Development activities, including experience of key staff members and

persons who will be providing the proposed Project activities and managing the Project;

(7) The method and rationale used to select the areas and businesses that will receive the service;

(8) A brief description of how the work will be performed including whether organizational staff or consultants or contractors will be used;

(9) Please note that no assistance or funding can be provided to hemp producers or processors unless they have a valid license issued from an approved State, Tribal or Federal plan as per Section 10113 of the Agriculture Improvement Act of 2018, Public Law 115-334. Verification of valid hemp licenses will occur at the time of award; and

(10) Other information the Agency may request to assist in making a grant award determination.

(e) The latest 3 years of financial information to show the applicant's financial capacity to carry out the proposed work. If the applicant is less than 3 years old, at a minimum, the information should include all balance sheet(s), income statement(s), and cash flow statement(s) since the date of the applicant's formation. A current financial statement of the applicant, within 90 days of the application submission, is required;

(f) Intergovernmental review comments from the State Single Point of Contact, or evidence that the State has elected not to review the program under Executive Order 12372. Applications from federally recognized tribes are exempt from this requirement;

(g) Documentation regarding the availability and amount of other funds to be used in conjunction with the funds from the RBDG award;

(h) A budget which includes salaries, fringe benefits, consultant costs, indirect costs, and other appropriate direct costs for the Project; and

(i) RBDG construction project grants must conform with 7 CFR part 1924, subpart A and the environmental policies and procedures of 7 CFR part 1970.

3. General Processing and Scoring Provisions.

The Agency will review each application for assistance in accordance with the scoring provisions and program priorities established in 7 CFR 4280.435. The Agency will assign each application a priority rating based on the total score and will select applications for funding based on the priority ratings and the total funds available to the program for opportunity-type projects and enterprise-type projects.

(a) The Agency will score each application based on the information contained in the application and its supporting information. All applications submitted for funding must be in one package and contain sufficient information to permit the Agency to complete a thorough priority rating. Agency employees may not consider any information that is not provided by the applicant in writing for scoring purposes. Applications will not be considered for funding if they do not provide sufficient information to determine eligibility or are missing required elements. Points will be awarded to an eligible application as follows:

- *Leveraging.* If the grant will fund a critical element of a larger program of Economic Development, without which the overall program either could not proceed or would be far less effective, or if the program to be assisted by the grant will also be partially funded from other sources, points will be awarded if Rural Development's funding is: (i) Less than 20 percent of the project costs—30 points; (ii) between 20 percent and up to 50 percent of the project—20 points; (iii) between 51 percent and up to 75 percent of the project—10 points. The application must contain a firm commitment in writing of other funding for the project or points will not be awarded to the application for leveraging.

- *Demographics.* Points will be awarded for each of the following criteria met by the community or communities that will receive the benefit of the grant, up to a total of 40 points from all categories: (i) Communities experiencing trauma due to a major natural disaster that occurred not more than 3 years prior to the filing of the application for assistance will be awarded 15 points; (ii) Communities that have suffered a loss of 20 percent or more in their total jobs caused by the closure of a military facility or other employers within the last 3 years will be awarded 15 points; (iii) Communities that have experienced Long-Term poverty as demonstrated by being a former Rural empowerment zone, Rural economic area partnership zone, Rural enterprise community, champion community, or a persistent poverty county as determined by USDA's Economic Research Service will receive 10 points; and (iv) If the community has experienced Long-Term population decline as demonstrated by the latest three decennial censuses, 10 points will be awarded.

- *Population.* Points will be awarded if the proposed project(s) will be located in a community of: (i) Under 5,000

population—15 points; (ii) Between 5,000 and up to 15,000 population—10 points; or (iii) Between 15,001 and 25,000 population—5 points.

- *Unemployment.* If the proposed project will be located in areas where the unemployment rate: (i) Exceeds the State rate by 25 percent or more—20 points will be awarded; (ii) exceeds the State rate by less than 25 percent—10 points will be awarded; or (iii) is equal to or less than the State unemployment rate—0 points will be awarded.

- *Median household income.* If the proposed project(s) will be located in areas where Median Household Income (MHI) as prescribed by section 673(2) of the Community Services Block Grant Act (42 U.S.C 106) for a family of 4 for the State is: (i) Less than or equal to the poverty line—25 points will be awarded; (ii) More than the poverty line but less than 65 percent of State MHI—15 points will be awarded; (iii) Between 65 and 85 percent of the State MHI—10 points will be awarded; or (iv) If the area has greater than 85 percent of the State MHI—0 points will be awarded.

- *Experience.* If the applicant provides evidence of successful experience in the type of activity proposed based on its current employees' resumes demonstrating: (i) 10 or more years of experience—30 points will be awarded; (ii) At least 5 but less than 10 years of experience—20 points will be awarded; (iii) At least 3 years but less than 5 years of experience—10 points will be awarded; or (iv) At least 1 but less than 3 years of experience—5 points will be awarded.

- *Small business start-up or expansion.* If the Applicant has evidence that small business development will be supported by startup or expansion as a result of the activities to be carried out under the grant by written evidence provided to the Agency from a small, or a Small and Emerging Business that includes the number of jobs that will be supported and created, 5 points will be awarded for each letter up to a total of 25 points. Letters must address the specific business producing the letter, the connection to the project activities and provide further information relative to job creation and support to meet the letter of support criteria. Generic or duplicated letters are not acceptable under this criterion.

- *Jobs created or supported.* Points will be awarded if the anticipated development, expansion, or furtherance of business enterprises as a result of the proposed Project will create and/or support existing jobs associated with the affected businesses. The number of jobs

must be evidenced by a written commitment from the business(es) to be assisted. Points will be awarded based on the ratio of jobs to be supported by the amount of grant funds. For projects supporting: (i) One job for less than \$5,000 of grant funds—25 points will be awarded; (ii) one job for \$5,000 but less than \$10,000 of grant funds—20 points; (iii) one job for \$10,000 but less than \$15,000—15 points; (iv) one job for \$15,000 but less than \$20,000—10 points; or (v) one job for \$20,000 but less than \$25,000 of grant funds—5 points will be awarded.

- *Size of grant request.* Projects utilizing grant funds of: (i) Less than \$100,000—25 points will be awarded; (ii) \$100,000 to \$200,000—15 points will be awarded; or (iii) more than \$200,000 but equal to or less than \$500,000—10 points will be awarded. No points will be awarded to applications of \$500,000 or greater.

- *Indirect cost.* If the applicant is not requesting grant funds to cover their administrative or indirect costs, 5 points will be awarded.

- *Discretionary points.* Either the State Director or Administrator may assign up to 50 discretionary points to an application when under their approval authority. Assignment of discretionary points must include a written justification. Permissible justifications are geographic distribution of funds, special Secretary of Agriculture initiatives such as Priority Communities, or a state's strategic goals. The number of points to be awarded will be determined by the impact of the project on the stated initiative. Discretionary points may only be assigned to initial grants. However, in the case where two Projects have the same score, the State Director may add one point to the Project that best fits the State's strategic plan regardless of whether the Project is an initial or subsequent grant. The following are examples of special Secretary of Agriculture initiatives that can support obtaining discretionary points.

- (i) *Assisting rural communities recover economically from the impacts of the COVID-19 pandemic, particularly disadvantaged communities.* Applicant may receive priority points if the project is located in or serving one of the top 10% of counties or county equivalents based upon county risk score in the United States. The website, <https://www.rd.usda.gov/priority-points>, has the data to confirm if your location qualifies or not.

- (ii) *Ensuring all rural residents have equitable access to RD programs and benefits from RD funded projects.* Applicant may receive priority points if

the project is located in or serving a community with score 0.75 or above on the CDC Social Vulnerability Index. The website, <https://www.rd.usda.gov/priority-points>, has the data to confirm if your location qualifies or not.

(iii) *Reduce climate pollution and increasing resilience to the impacts of climate change through economic support to rural communities.*

Applicants may receive points if the project is located in or serving coal, oil and gas, and power plant communities whose economic well-being ranks in the most distressed tier of the Distressed Communities Index. The website, <https://www.rd.usda.gov/priority-points>, has the data to confirm if your location qualifies or not. Or, applicants may receive points by demonstrating how proposed climate-impact projects improve the livelihoods of community residents and meet pollution mitigation or clean energy goals.

(b) *Unfunded applications.* The Agency will notify eligible applicants in writing if RBDG funds are not available. The applicant is permitted to respond in writing that they wish their application to be reconsidered in the next fiscal year. The applicant may provide additional updated information to the Agency prior to the next fiscal year's application deadline for their project.

(c) *Unfunded applications for set aside funding.* The Agency will notify eligible applicants in writing if set aside funds are not available. Applications that are eligible for set aside funds but are unfunded due to the availability of funds will be allowed to compete for available FY 2022 regular RBDG funds in the State where the Project is located. For Projects involving multiple states, the application will be returned to the Rural Development State Office where the Applicant is located and will compete for funds in that State. The Agency will notify eligible applicants in writing if their application will not be funded in FY 2022 due to insufficient funds in the set aside and regular RBDG programs.

D. Application and Submission Information

1. Address to Request Application Package.

For further information, entities wishing to apply for assistance should contact the USDA Rural Development State Office provided in the **ADDRESSES** section of this notice to obtain copies of the application package.

Prior to official submission of grant applications, applicants may request technical assistance or other application guidance from the Agency, as long as such requests are made prior to

February 11, 2022. Technical assistance is not meant to be an analysis or assessment of the quality of the materials submitted, a substitute for agency review of completed applications, nor a determination of eligibility.

The Agency will not solicit or consider scoring or eligibility information that is submitted after the application deadline. The Agency reserves the right to contact applicants to seek clarification information on materials contained in the submitted application.

Applications may be submitted in paper or electronic format to the appropriate Rural Development State Office and must be received by 4:30 p.m. local time on February 28, 2022. Applicants are encouraged to contact their respective Rural Development State Office for an email contact to submit an electronic application prior to the submission deadline date(s). All applicants must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number which can be obtained at no cost via a toll-free request line at: (866) 705-5711 or at <http://fedgov.dnb.com/webform>. Each applicant applying for grant funds (unless the applicant is an individual or Federal awarding agency that is excepted from the requirements under 2 CFR 25.110(b) or (c) or has an exception approved by the Federal awarding agency under 2 CFR 25.110(d)) is required to: (i) Be registered in the System for Award Management (SAM) before submitting its application; (ii) provide a valid unique entity identifier in its application; and (iii) continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency. The Federal awarding agency may not make a Federal award to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements and, if an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

2. Content and Form of Application Submission.

An application must contain all of the required elements and be submitted in one package. Each selection priority criterion outlined in 7 CFR 4280.427 must be addressed in the application.

Failure to address any of the criterion will result in a zero-point score for that criterion and will impact the overall evaluation of the application. An original copy of the application must be filed with the Rural Development State Office for the State where the Project is located. For Projects involving multiple states, the application must be filed in the Rural Development State Office where the Applicant is located.

The applicant documentation and forms needed for a complete application are located in the PROGRAM DESCRIPTION section of this notice, and in 7 CFR part 4280, subpart E, a copy of which will be provided to any interested applicant making a request to a Rural Development State Office. There are no specific formats required per this notice, and applicants may request forms and addresses from the **ADDRESSES** section of this notice. Any form that requires an original signature but is signed electronically in the application submission must be signed in ink by the authorized person prior to the disbursement of funds.

(a) There are no specific limitations on the number of pages or other formatting requirements other than those described in the PROGRAM DESCRIPTION section.

(b) There are no specific limitations on the number of pages, font size and type face, margins, paper size, and the sequence or assembly requirements but the application package should be well organized and include a table of contents, if appropriate.

(c) The component pieces of this application should contain original signatures on the original application.

3. Submission Dates and Times.

(a) *Application Deadline Dates:* Applications must be submitted to the appropriate Rural Development State Office no later than 4:30 p.m. (local time) on February 28, 2022.

(b) The deadline date means that the completed application package must be received in the USDA Rural Development State Office by the established deadline date and time. All application documents identified in this notice are required in the submission to be considered a complete application. The Agency will determine the application receipt date for paper applications based on the actual date postmarked. The date of receipt for electronic application submissions will be the date received in the Rural Development State Office by the designated Agency staff person.

(c) If completed applications are not received by the February 28, 2022, deadline, the application will neither be

reviewed nor considered for funding under any circumstances.

(d) Indirect costs will be permitted in accordance with applicable law and in accordance with 2 CFR part 200. Pre-Federal award costs will only be permitted with prior written approval by the Agency.

(e) Applicants may submit applications in hard copy or electronic format as previously indicated in the Application and Submission Information section of this notice. If the applicant wishes to hand deliver its application, the addresses for these deliveries are located in the ADDRESSES section of this notice.

(f) If you require alternative means of communication for program information (e.g., Braille, large print, audiotape, etc.) please contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

E. Application Review Information

1. Criteria.

All eligible and complete applications will be evaluated and scored based on the selection criteria and weights contained in 7 CFR part 4280, subpart E. Failure to address any one of the criteria by the application deadline will result in the application being determined ineligible, and the application will not be considered for funding.

2. Review and Selection Process.

The Rural Development State Offices will review applications to determine if they are eligible for assistance based on requirements contained in 7 CFR 4280.416 and 7 CFR 4280.417. Funding of projects is subject to the availability of funds and Applicant's satisfactory submission of the items required by 7 CFR part 4280, subpart E and this Notice, in addition to any conditions specifically outlined in any issued USDA Rural Development Letter of Conditions if available funds are to be awarded.

Applications for set aside funds, if available, will compete at the National Office in their respective categories. Applications for regular RBDG projects will compete at the state level in their respective category, business opportunity grants or business enterprise grants, for funding made available through Rural Development State allocated funds. Applications will be reviewed, prioritized by score, and funded by ranking each Project in highest to lowest score order until available funds are exhausted. If funds are exhausted at the state level, each State's highest scoring unfunded business enterprise project will have the opportunity to compete for funding through a final national competition.

F. Federal Award Administration Information

1. Federal Award Notices.

Successful applicants will receive notification for funding from the Rural Development State Office. Applicants must comply with all applicable statutes and regulations before the grant award can be approved and funded. If an application is withdrawn by the applicant, it can be resubmitted later and will be evaluated as a new application in the period submitted.

2. Administrative and National Policy Requirements.

Additional requirements that apply to grantees selected for this Program can be found in 7 CFR part 4280, subpart E. Awards are subject to USDA grant regulations at 2 CFR part 400 which incorporated the Office of Management and Budget (OMB) regulations at 2 CFR part 200.

All successful applicants will be notified by letter which will include a Letter of Conditions and a Letter of Intent to Meet Conditions. This letter is not an authorization to begin performance, but it is a notification that grant funds may be awarded subject to conditions. The grant will be considered officially awarded when all conditions in the Letter of Conditions have been met and the Agency obligates the funding for the Project. If the applicant wishes to consider beginning their project performance prior to the grant being officially closed, all pre-award costs must be approved in writing and in advance by the Agency.

Additional requirements that apply to grantees selected for these Programs can be found in 7 CFR part 4280, subpart E, the Grants and Agreements regulations of the U.S. Department of Agriculture codified in 2 CFR 400.1 to 400.2 and 2 CFR parts 415 to 422, and successor regulations to these parts.

In addition, all recipients of Federal financial assistance are required to report information about first-tier sub-awards and executive compensation (see 2 CFR part 170). The applicant will be required to have the necessary processes and systems in place to comply with the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109-282) reporting requirements (see 2 CFR 170.200(b), unless the recipient is exempt under 2 CFR 170.110(b)).

The following additional requirements apply to grantees selected for these Programs:

(a) Form RD 4280-2 "Rural Business-Cooperative Service Financial Assistance Agreement."

(b) Letter of Conditions.

(c) Form RD 1940-1, "Request for Obligation of Funds."

(d) Form RD 1942-46, "Letter of Intent to Meet Conditions."

(e) SF LLL, "Disclosure of Lobbying Activities," if applicable.

(f) Grantees will use Form SF 270, "Request for Advance or Reimbursement" when requesting grant funds from the Agency.

3. Reporting.

(a) A Financial Status Report and a Project performance activity report will be required of all grantees on a quarterly basis until initial funds are expended and yearly thereafter, if applicable, based on the Federal fiscal year. Grantees must continuously monitor performance to ensure that time schedules are being met, projected work by time periods is being accomplished, and other performance objectives are being achieved. Grantees must submit an original of each report to the Agency no later than 30 days after the end of the quarter. The grantee will complete the Project within the total time available to it in accordance with the Scope of Work and any necessary modifications thereof prepared by the grantee and approved by the Agency. A final Project performance report will be required with the final Financial Status Report. The final report may serve as the last quarterly report. The final report must provide complete information regarding the jobs created and supported as a result of the RBDG grant if applicable. The Project performance reports must include, but not be limited to, the following:

(1) A comparison of actual accomplishments to the objectives established for that period.

(2) Problems, delays, or adverse conditions, if any, which have affected or will affect attainment of overall Project objectives, prevent meeting time schedules or objectives, or preclude the attainment of particular Project work elements during established time periods. This disclosure shall be accompanied by a statement of the action taken or planned to resolve the situation.

(3) Objectives and timetable established for the next reporting period.

(4) Any special reporting requirements, such as jobs supported and created, businesses assisted, or economic development which results in improvements in median household incomes, and any other specific requirements, will be placed in the reporting section of the Letter of Conditions.

(5) Within 90 days after the conclusion of the Project, the grantee

will provide a final Project evaluation report. The last quarterly payment will be withheld until the final report is received and approved by the Agency. Even though the grantee may request reimbursement on a monthly basis, the last 3 months of reimbursements will be withheld until a final report, Project performance, and financial status report are received and approved by the Agency.

(b) In addition to any reports required by 2 CFR part 200 and 2 CFR 400.1 to 400.2, and 2 CFR parts 415 to 422, the grantee must provide reports as required by 7 CFR part 4280, subpart E.

G. Federal Awarding Agency Contact(s)

For general questions about this announcement, please contact your USDA Rural Development State Office provided in the **ADDRESSES** section of this notice.

H. Civil Rights Requirements

All grants made under this notice are subject to Title VI of the Civil Rights Act of 1964 as required by the USDA (7 CFR part 15, subpart A) and Section 504 of the Rehabilitation Act of 1973, Title VIII of the Civil Rights Act of 1968, Title IX, Executive Order 13166 (Limited English Proficiency), Executive Order 11246, and the Equal Credit Opportunity Act of 1974.

I. Other Information

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the information collection requirement contained in this notice is approved by OMB under OMB Control Number 0570-0070.

Federal Funding Accountability and Transparency Act

All applicants, in accordance with 2 CFR part 25, must have a DUNS number, which can be obtained at no cost via a toll-free request line at (866) 705-5711 or online at <http://fedgov.dnb.com/webform>. Similarly, all applicants applying for grant funds must be registered in SAM prior to submitting an application. Applicants may register for the SAM at <http://www.sam.gov/SAM>. All recipients of Federal financial grant assistance are required to report information about first-tier sub-awards and executive total compensation in accordance with 2 CFR part 170.

Nondiscrimination Statement

In accordance with Federal civil rights laws and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Mission Areas, agencies, staff offices,

employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (e.g., Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720-2600 (voice and TTY); or the Federal Relay Service at (800) 877-8339.

To file a program discrimination complaint, a complainant should complete a Form AD-3027, USDA Program Discrimination Complaint Form, which can be obtained online at <https://www.ocio.usda.gov/document/ad-3027>, from any USDA office, by calling (866) 632-9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD-3027 form or letter must be submitted to USDA by:

(1) *Mail*: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410; or

(2) *Fax*: (833) 256-1665 or (202) 690-7442; or

(3) *Email*: program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.

Karama Neal,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2021-20810 Filed 9-24-21; 8:45 am]

BILLING CODE 3410-XY-P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Maryland Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of planning meeting and briefings.

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 briefings of the Maryland Advisory Committee to the Commission will convene by WebEx virtual platform and conference call on Tuesday, October 5, 2021, at 12:00 p.m. (ET) for continued planning on the water affordability project. The Committee will also convene briefings by WebEx virtual platform and conference at 12:00 p.m. (ET) on Tuesday, November 2; Thursday, November 4; Tuesday, November 9; and Tuesday, November 16, 2021. The purpose of the briefings is to hear from government officials, advocates, experts, academicians, the public, and others on water accessibility and affordability in Maryland.

DATES: Tuesday, October 5; Tuesday, November 2; Thursday, November 4; Tuesday, November 9; and Tuesday, November 16, 2021; 12:00 p.m. (ET).

Public WebEx Conference Links (Video and Audio)

Link for 10/5/21 (Tuesday); 12:00 p.m. (ET): <https://bit.ly/2XBJZbg>

Link for 11/2, 11/9, and 11/16/21 (Tuesdays); 12:00 p.m. (ET): <https://bit.ly/3CgyiWn>

Link for 11/4/21 (Thursday); 12:00 p.m. (ET): <https://bit.ly/2Z4fF9Q>

IF PHONE ONLY on 10/5/21: 1-800-360-9505; Access code: 1998 18 3090

IF PHONE ONLY on 11/2/21, 11/9/21, 11/16/21: 1-800-360-9505; Access code: 2764 724 3858

IF PHONE ONLY on 11/4/21: 1-800-360-9505; Access code: 2760 387 4133

FOR FURTHER INFORMATION CONTACT:

Barbara Delaviez at ero@usccr.gov or by phone at 202-381-8915.

SUPPLEMENTARY INFORMATION: The meeting is available to the public through the web link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1-800-877-8339 and providing the Service with conference

details found through registering at the web link above. To request additional accommodations, please email bdelaviez@usccr.gov at least 10 days prior to the meeting.

Members of the public are invited to make statements during the open comment period of the meeting or submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be emailed to Barbara Delaviez at ero@usccr.gov. Persons who desire additional information may contact Barbara Delaviez at 202-539-8246.

Records and documents discussed during the meeting will be available for public viewing as they become available at www.facadatabase.gov. 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 or email address.

Agenda

Oct. 5, Nov. 2, Nov. 4, Nov. 9, and Nov. 16; 12:00 p.m. (ET)

- Rollcall
- Planning Meeting: Oct. 5
- Briefings on Water Affordability/Accessibility: Nov. 2, Nov. 4, Nov. 9, Nov. 16
- Next Steps and Other Business
- Open Comment
- Adjournment

Dated: September 21, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021-20809 Filed 9-24-21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Services Surveys: BE-185, Quarterly Survey of Financial Services Transactions Between U.S. Financial Services Providers and Foreign Persons

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance, in accordance with the Paperwork Reduction Act of 1995 (PRA), on or after the date of publication of this notice. We invite the

general public and other Federal agencies to comment on proposed and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on May 26, 2021, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Bureau of Economic Analysis, Department of Commerce.

Title: Quarterly Survey of Transactions Between U.S. Financial Services Providers and Foreign Persons.

OMB Control Number: 0608-0065.

Form Number(s): BE-185.

Type of Request: Regular submission, extension of a current information collection.

Number of Respondents: 2,860 annually (715 filed each quarter; 580 reporting mandatory data, and 135 that would file exemption claims or voluntary responses).

Average Hours per Response: 10 hours is the average for those reporting data and one hour is the average for those filing an exemption claim. Hours may vary considerably among respondents because of differences in company size and complexity.

Burden Hours: 24,140 hours annually.

Needs and Uses: The data are needed to monitor U.S. trade in financial services, to analyze the impact of these cross-border services on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the trade in financial services component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

Affected Public: Business or other for-profit organizations.

Frequency: Quarterly.

Respondent's Obligation: Mandatory.

Legal Authority: International Investment and Trade in Services Survey Act (Pub. L. 94-472, 22 U.S.C. 3101-3108, as amended), and Section 5408 of the Omnibus Trade and Competitiveness Act of 1988.

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

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the

publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function and entering either the title of the collection or the OMB Control Number 0608-0065.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021-20945 Filed 9-24-21; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 210902-0176]

RIN 0694-XC083

Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Neodymium-Iron-Boron (NdFeB) Permanent Magnets

AGENCY: Bureau of Industry and Security, Office of Technology Evaluation, U.S. Department of Commerce.

ACTION: Notice of request for public comments.

SUMMARY: On September 21, 2021, the Secretary of Commerce (Secretary) initiated an investigation to determine the effects on the national security from imports of neodymium-iron-boron (NdFeB) permanent magnets (sometimes referred to as neodymium magnets, neo magnets, or rare earth magnets). This investigation has been initiated under section 232 of the Trade Expansion Act of 1962, as amended. While the Department is interested in any information related to this investigation that the public can provide, this notice identifies particular issues of significance.

DATES: Interested parties are invited to submit written comments, data, analyses, or other information pertinent to the investigation to the Department of Commerce's (Department) Bureau of Industry and Security by November 12, 2021. The due date for filing comments is November 12, 2021.

ADDRESSES: *Submissions:* You may submit comments, identified by docket number BIS 2021-0035 or RIN 0694-XC083, through the *Federal eRulemaking Portal*: <http://www.regulations.gov>. To submit comments via <https://>

www.regulations.gov, enter docket number BIS–2021–0035 on the home page and click “search.” The site will provide a search results page listing all documents associated with this docket. Find a reference to this notice and click on the link entitled “Comment Now!” (For further information on using <https://www.regulations.gov>, please consult the resources provided on the website by clicking on “How to Use This Site.”)

FOR FURTHER INFORMATION CONTACT:

David Boylan, Industrial Studies Division, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482–0194, NdFeB232@bis.doc.gov. For more information about the section 232 program, including the regulations and the text of previous investigations, please see www.bis.doc.gov/232.

SUPPLEMENTARY INFORMATION:

Background

On September 21, 2021, the Secretary initiated an investigation under section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862), to determine the effects on the national security from imports of NdFeB permanent magnets. Numerous critical national security systems rely on NdFeB permanent magnets, including fighter aircraft and missile guidance systems. In addition, NdFeB permanent magnets are essential components of critical infrastructure, including electric vehicles and wind turbines. The magnets are also used in computer hard drives, audio equipment, and MRI devices. If the Secretary finds that NdFeB permanent magnets are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security, the Secretary shall so advise the President in her report on the findings of the investigation.

Written Comments

This investigation is being undertaken in accordance with part 705 of the National Security Industrial Base Regulations (15 CFR parts 700 to 709) (“NSIBR”). Interested parties are invited to submit written comments, data, analyses, or information pertinent to this investigation to the Department’s Office of Technology Evaluation no later than November 12, 2021.

The Department is particularly interested in comments and information directed to the criteria listed in § 705.4 of the NSIBR as they affect national security, including the following:

(i) Quantity of or other circumstances related to the importation of NdFeB permanent magnets;

(ii) Domestic production and productive capacity needed for NdFeB permanent magnets to meet projected national defense requirements;

(iii) Existing and anticipated availability of human resources, products, raw materials, production equipment, and facilities to produce NdFeB permanent magnets;

(iv) Growth requirements of the NdFeB permanent magnets industry to meet national defense requirements and/or requirements for supplies and services necessary to assure such growth including investment, exploration, and development;

(v) The impact of foreign competition on the economic welfare of the domestic NdFeB permanent magnets industry;

(vi) The displacement of any domestic NdFeB permanent magnets production causing substantial unemployment, decrease in the revenues of government, loss of investment or specialized skills and productive capacity, or other serious effects;

(vii) Relevant factors that are causing or will cause a weakening of our national economy; and

(viii) Any other relevant factors, including the use and importance of NdFeB permanent magnets in critical infrastructure sectors identified in Presidential Policy Directive 21 (Feb. 12, 2013) (for a listing of those 16 sectors see <https://www.dhs.gov/cisa/critical-infrastructure-sectors>).

Requirements for Written Comments

The <https://www.regulations.gov> website allows users to provide comments by filling in a “Type Comment” field, or by attaching a document using an “Upload File” field. The Department prefers that comments be provided in an attached document. The Department prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application format other than those two, please indicate the name of the application in the “Type Comment” field. Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible please include any exhibits, annexes, or other attachments in the same file (as part of the submission itself) rather than in separate files. Comments will be placed in the docket and open to public inspection, except information determined to be confidential as set forth in § 705.6 of the NSIBR. Comments may be viewed on <https://www.regulations.gov> by entering docket number BIS–2021–0035 in the search field on the home page.

Material submitted by members of the public that is properly marked business confidential information and accepted as such by the Department will be exempted from public disclosure as set forth in § 705.6 of the NSIBR. All filers using the portal should use the name of the person or entity submitting comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and also provide a non-confidential version of the submission in a separate file.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters “BC.” Any page containing business confidential information must be clearly marked “BUSINESS CONFIDENTIAL” on the top of that page. The corresponding non-confidential version of those comments must be clearly marked “PUBLIC.” The file name of the non-confidential version should begin with the character “P.” The “BC” and “P” should be followed by the name of the person or entity submitting the comments or rebuttal comments. Any submissions with file names that do not begin with a “BC” or “P” will be assumed to be public and will be made publicly available through <http://www.regulations.gov>.

The Bureau of Industry and Security does not maintain a separate public inspection facility. Requesters should first view the Bureau of Industry and Security web page, which can be found at <https://efoia.bis.doc.gov/> (see the link to the Index of Documents under the “Electronic FOIA” heading on the web page). If requesters cannot access the website, they may call 202–482–0795 for assistance. The records related to this assessment are made accessible in accordance with the regulations published in part 4 of title 15 of the Code of Federal Regulations (15 CFR 4.1 *et seq.*).

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2021–20903 Filed 9–24–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C-489-819]

Steel Concrete Reinforcing Bar From the Republic of Turkey: Final Results of Countervailing Duty Administrative Review and Rescission, in Part; 2018

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

SUMMARY: The Department of Commerce (Commerce) determines that certain producers/exporters of steel concrete reinforcing bar (rebar) from the Republic of Turkey (Turkey) received countervailable subsidies during the period of review (POR) January 1, 2018, through December 31, 2018. Additionally, we are rescinding the review for 21 companies with no shipments of subject merchandise to the United States during the POR.

DATES: Applicable September 27, 2021.

FOR FURTHER INFORMATION CONTACT: Konrad Ptaszynski, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-6187, respectively.

SUPPLEMENTARY INFORMATION:**Background**

Commerce published the *Preliminary Results* of this review on March 25, 2021,¹ and invited comments from interested parties. On June 25, 2021, Commerce extended the deadline to issue the final results of this review until September 21, 2021.² For a complete description of the events that occurred since the *Preliminary Results*, see the Issues and Decision Memorandum.³

¹ See *Steel Concrete Reinforcing Bar from the Republic of Turkey: Preliminary Results of Countervailing Duty Administrative Review and Intent To Rescind in Part; 2018*, 86 FR 15921 (March 25, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

² See Memorandum, "Steel Concrete Reinforcing Bar from the Republic of Turkey: Extension of Deadline for Final Results of Countervailing Duty Administrative Review; 2018," dated June 25, 2021.

³ See Memorandum, "Issues and Decision Memorandum for the Final Results of the 2018 Administrative Review of the Countervailing Duty Order of Steel Concrete Reinforcing Bar from the Republic of Turkey," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Scope of the Order⁴

The merchandise covered by the Order is steel concrete reinforcing bar (rebar). For a complete description of the scope, see the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs filed by interested parties in this review are listed in the appendix to this notice and addressed in the Issues and Decision Memorandum. 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>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/>.

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results*, and for the reasons explained in the Issues and Decision Memorandum, we made certain changes for these final results of review.

Methodology

Commerce conducted this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.*, a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.⁵ For a description of the methodology underlying all of Commerce's conclusions, see the Issues and Decision Memorandum.

Rescission of Administrative Review, in Part

It is Commerce's practice to rescind an administrative review of a countervailing duty order, pursuant to 19 CFR 351.213(d)(3), when there are no reviewable entries of subject merchandise during the POR for which liquidation is suspended.⁶ Normally,

⁴ See *Steel Concrete Reinforcing Bar from the Republic of Turkey: Countervailing Duty Order*, 79 FR 65926 (November 6, 2014) (*Order*).

⁵ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

⁶ See, *e.g.*, *Lightweight Thermal Paper from the People's Republic of China: Notice of Rescission of Countervailing Duty Administrative Review; 2015*,

upon completion of an administrative review, the suspended entries are liquidated at the countervailing duty assessment rate calculated for the review period.⁷ Therefore, for an administrative review of a company to be conducted, there must be a reviewable, suspended entry that Commerce can instruct U.S. Customs and Border Protection (CBP) to liquidate at the calculated countervailing duty assessment rate calculated for the review period.⁸

According to the CBP import data, except for the two mandatory respondents and two other companies (Colakoglu Dis Ticaret A.S. and Colakoglu Metalurji A.S.), the remaining 21 companies subject to this review did not have reviewable entries of subject merchandise during the POR for which liquidation is suspended.⁹ Because there is no evidence on the record of this segment of the proceeding to indicate that these companies had entries, exports, or sales of subject merchandise to the United States during the POR, we are rescinding the administrative review with respect to these companies consistent with 19 CFR 351.213(d)(3).

Rate for Non-Selected Companies Under Review

There are two companies for which a review was requested but which were not selected as mandatory respondents or found to be cross-owned with a mandatory respondent. Because the rate calculated for the mandatory respondent, Kaptan, was above *de minimis* and not based entirely on facts available, we applied the subsidy rate calculated for Kaptan to these two non-selected companies. This methodology for establishing the subsidy rate for the non-selected companies is consistent

82 FR 14349 (March 20, 2017); see also *Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2017*, 84 FR 14650 (April 11, 2019).

⁷ See 19 CFR 351.212(b)(2).

⁸ See 19 CFR 351.213(d)(3).

⁹ The 21 companies are: (1) Acemar International Limited; (2) A G Royce Metal Marketing; (3) Agir Haddecilik A.S.; (4) As Gaz Sinai ve Tibbi Gazlar A.S.; (5) Asil Celik Sanayi ve Ticaret A.S.; (6) Atakas Celik Sanayi ve Ticaret A.S.; (7) Bastug Metalurji Sanayi AS; (8) Demirsan Haddecilik Sanayi Ve Ticaret AS; (9) Diler Dis Ticaret AS; (10) Duferco Investment Services SA; (11) Duferco Celik Ticaret Limited; (12) Ege Celik Endustrisi Sanayi ve Ticaret A.S.; (13) Ekinciler Demir ve Celik Sanayi Anonim Sirketi; (14) Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S. (Habas); (15) Izmir Demir Celik Sanayi A.S.; (16) Kibar Dis Ticaret A.S.; (17) Kocaer Haddecilik Sanayi ve Ticar; (18) Mettech Metalurji Madencilik Muhendislik Uretim Danismanlik ve Ticaret Limited Sirketi; (19) MMZ Onur Boru Profil A.S.; (20) Ozkan Demir Celik Sanayi A.S.; and (21) Wilmar Europe Trading B.V.

with our practice and with section 705(c)(5)(A) of the Act.

Final Results of the Administrative Review

We find the following net countervailable subsidy rates for the POR January 1, 2018, through December

Company	Subsidy rate (percent <i>ad valorem</i>)
Icdas Celik Enerji Tersane ve Ulasim Sanayi A.S. and its cross-owned affiliates ¹⁰	0.32 (<i>de minimis</i>)
Kaptan Demir Celik Endustrisi ve Ticaret A.S. and Kaptan Metal Dis Ticaret ve Nakliyat A.S. and their cross-owned affiliates ¹¹	1.82
Colakoglu Dis Ticaret A.S.	1.82
Colakoglu Metalurji A.S.	1.82

Disclosure 31, 2018:

Commerce intends to disclose the calculations and analysis performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Requirements

In accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries covered by this review. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(1) of the Act, we also intend to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown above for the above-listed companies with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of these final results of review. For all non-reviewed firms, CBP

¹⁰ Commerce finds the following companies to be cross-owned with Icdas: Mardas Marmara Deniz Isletmeciligi A.S.; Oraysan Insaat Sanayi ve Ticaret A.S.; Artim Demir Insaat Turizm Sanayi Ticaret Ltd. Sti.; Anka Entansif Hayvancilik Gida Tarim Sanayi ve Ticaret A.S.; Karsan Gemi Insaat Sanayi Ticaret A.S.; Artnak Denizcilik Ticaret Ve Sanayi A.S.; and Eras Tasimacilik Taahhut Ins.Tic.A.S.

¹¹ Commerce finds the following companies to be cross-owned with Kaptan: Martas Marmara Ereglisi Liman Tesisleri A.S.; Aset Madencilik A.S.; Kaptan Is Makinalari Hurda Alim Satim Ltd. Sti.; Efesan Demir San. Ve Tic. A.S.; and Nur Gemicilik ve Tic. A.S.

will continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

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 disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or 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 sanctionable violation.

Notification to Interested Parties

The final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4) and 19 CFR 351.221(b)(5).

Dated: September 21, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Rescission of Administrative Review, In Part
- V. Subsidies Valuation Information
- VI. Analysis of Programs
- VII. Discussion of the Issues
 - Comment 1: Whether Commerce Should Countervail Import Duty Exemptions Under the Inward Processing Regime (IPR) Program
 - Comment 2: Whether Commerce Should Countervail the Provision of Lignite for

Less than Adequate Remuneration (LTAR)

Comment 3: Whether Commerce Should Countervail the Provision of Natural Gas for LTAR

Comment 4: Whether Commerce Should Revise the Sales Denominators That It Used in the Preliminary Results for Icdas and Kaptan

Comment 5: Whether Commerce Should Revise its Finding that Nur Gemicilik ve Tic. A.S. (Nur) is a Cross-Owned Input Supplier

Comment 6: Whether Commerce Should Revise Its Finding That Nur's Land Rent Exemption is Countervailable

Comment 7: Whether Commerce Should Reduce Its Calculation of Benefits Attributed to Icdas for Renewable Energy Sources Support Mechanism (YEKDEM) Support by the Amount Reclaimed

Comment 8: Whether Commerce Should Revise Its Benchmark Interest Rate Calculations to Include All Short-Term Commercial Loans in Effect During the POR

VIII. Recommendation

[FR Doc. 2021-20906 Filed 9-24-21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No.: 210914-0185]

National Cybersecurity Center of Excellence (NCCoE) Addressing Visibility Challenges With TLS 1.3

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) invites organizations to provide letters of interest describing products and technical expertise to support and demonstrate security platforms for the *Addressing Visibility Challenges With TLS 1.3* project. This notice is the initial step for the National Cybersecurity

Center of Excellence (NCCoE) in collaborating with technology companies to address cybersecurity challenges identified under the *Addressing Visibility Challenges With TLS 1.3* project. Participation in the project is open to all interested organizations.

DATES: Collaborative activities will commence as soon as enough completed and signed letters of interest have been returned to address all the necessary components and capabilities, but no earlier than October 27, 2021.

ADDRESSES: The NCCoE is located at 9700 Great Seneca Highway, Rockville, MD 20850. Letters of interest must be submitted to applied-crypto-visibility@nist.gov or via hardcopy to National Institute of Standards and Technology, NCCoE; 9700 Great Seneca Highway, Rockville, MD 20850. Interested parties can access the letter of interest template by visiting <https://www.nccoe.nist.gov/projects/building-blocks/applied-cryptography/cmvp-automation> and completing the letter of interest webform. NIST will announce the completion of the selection of participants and inform the public that it will no longer accept letters of interest for this project at <https://www.nccoe.nist.gov/projects/building-blocks/applied-cryptography/addressing-visibility-challenges-tls-13>. Organizations whose letters of interest are accepted will be asked to sign a consortium Cooperative Research and Development Agreement (CRADA) with NIST. An NCCoE consortium CRADA template can be found at: <https://nccoe.nist.gov/library/nccoe-consortium-crada-example>.

FOR FURTHER INFORMATION CONTACT: Tim Polk via phone (301) 975-0225 or email applied-crypto-visibility@nist.gov; by mail to National Institute of Standards and Technology, NCCoE; 9700 Great Seneca Highway, Rockville, MD 20850. Additional details about the *Addressing Visibility Challenges With TLS 1.3* project are available at <https://www.nccoe.nist.gov/projects/building-blocks/applied-cryptography/addressing-visibility-challenges-tls-13>.

SUPPLEMENTARY INFORMATION:

Background: The NCCoE, part of NIST, is a public-private collaboration for accelerating the widespread adoption of integrated cybersecurity tools and technologies. The NCCoE brings together experts from industry, government, and academia under one roof to develop practical, interoperable cybersecurity approaches that address the real-world needs of complex Information Technology (IT) systems. By accelerating dissemination and use

of these integrated tools and technologies for protecting IT assets, the NCCoE will enhance trust in U.S. IT communications, data, and storage systems; reduce risk for companies and individuals using IT systems; and encourage development of innovative, job-creating cybersecurity products and services.

Process: NIST is soliciting responses from all sources of relevant security capabilities (see below) to enter into a Cooperative Research and Development Agreement (CRADA) to provide products and technical expertise to support and demonstrate security platforms for the *Addressing Visibility Challenges With TLS 1.3* project. The full project can be viewed at: <https://www.nccoe.nist.gov/projects/building-blocks/applied-cryptography/addressing-visibility-challenges-tls-13>.

Interested parties can access the template for a letter of interest by visiting the project website at <https://www.nccoe.nist.gov/projects/building-blocks/applied-cryptography/addressing-visibility-challenges-tls-13> and completing the letter of interest webform. On completion of the webform, interested parties will receive access to the letter of interest template, which the party must complete, certify as accurate, and submit to NIST by email or hardcopy. NIST will contact interested parties if there are questions regarding the responsiveness of the letters of interest to the project objective or requirements identified below. NIST will select participants who have submitted complete letters of interest on a first come, first served basis within each category of product components or capabilities listed below up to the number of participants in each category necessary to carry out this project. When the project has been completed, NIST will post a notice on the *Addressing Visibility Challenges With TLS 1.3* project website at <https://www.nccoe.nist.gov/projects/building-blocks/applied-cryptography/addressing-visibility-challenges-tls-13> announcing the completion of the project and informing the public that it will no longer accept letters of interest for this project. Completed letters of interest should be submitted to NIST and will be accepted on a first come, first served basis. There may be continuing opportunity to participate even after initial activity commences for participants who were not selected initially or have submitted the letter of interest after the selection process. Selected participants will be required to enter into a consortium CRADA with NIST (for reference, see **ADDRESSES** section above).

Project Objective: Deployment of new protocols for exchanging encrypted information, in particular the latest version of the Transport Layer Security (TLS) protocol, TLS 1.3, can impact the ability of some organizations to meet their regulatory, security, and operational requirements due to loss of visibility into the content of communications within their environments. The objective of this project is to demonstrate practical and implementable approaches to help those organizations adopt TLS 1.3 in their private data centers and in hybrid cloud environments while meeting their existing requirements. The proposed proof-of-concept solution(s) will integrate commercial and open source products that leverage cybersecurity standards and recommended practices to demonstrate the use case scenarios detailed in the *Addressing Visibility Challenges with TLS 1.3* project description at <https://www.nccoe.nist.gov/projects/building-blocks/applied-cryptography/addressing-visibility-challenges-tls-13>. This project will result in a publicly available NIST Cybersecurity Practice Guide as a Special Publication 1800 series, a detailed implementation guide describing the practical steps needed to implement a cybersecurity reference implementation.

Requirements for Letters of Interest: Each responding organization's letter of interest should identify which security platform component(s) or capability(ies) it is offering. Letters of interest should not include company proprietary information, and all components and capabilities must be commercially available. Components are listed in section 3 of the *Addressing Visibility Challenges with TLS 1.3* project description at <https://www.nccoe.nist.gov/projects/building-blocks/applied-cryptography/addressing-visibility-challenges-tls-13> and include, but are not limited to:

- Network infrastructure, such as firewalls, routers and switches, and load balancers
- Physically hosted and cloud-based servers, network-attached storage, application servers, web servers, databases, and identity management systems
- Additional components required to achieve visibility (e.g., traffic collection or sensors), as identified in proposed solutions

Each responding organization's letter of interest should identify how their products help address one or more of the following desired security characteristics and properties in section

3 of the *Addressing Visibility Challenges with TLS 1.3* project description at <https://www.nccoe.nist.gov/projects/building-blocks/applied-cryptography/addressing-visibility-challenges-tls-13>:

- Proposed contributions must support addressing security, operational, or compliance requirements where traffic is encrypted between one or more sets of components in the demonstration architecture. For example, a solution might focus on achieving visibility into information exchanges between cloud-hosted application servers to support troubleshooting. Alternatively, a solution might analyze information exchanges between physically hosted web servers with hardware security modules and cloud-based services relying on software-based cryptographic modules to monitor for fraudulent transactions. Solutions are not required to address all challenges or all components in the architecture, although comprehensive solutions are strongly encouraged.

- The use of visibility technologies within the enterprise data center environment is generally acceptable in ways that visibility technologies on the public internet may not be. However, contributions that forgo forward secrecy within the enterprise must be deployable in a manner that preserves forward secrecy for information exchanges over the internet if they are to be accepted.

- While visibility challenges are not limited to a single protocol, the focus for this project is TLS 1.3. Proposed contributions must be compatible with TLS 1.3, excepting those solutions relying upon an alternative network security protocol as a replacement for TLS. That is, proposed contributions that modify TLS 1.3 or restrict enterprises to earlier version of TLS will not be considered.

- Contributions must support scalable solutions.

- Contributions must support solutions that are relatively easy to implement/deploy.

- Contributions must support solutions that are protocol agnostic.

- Contributions must support solutions that are usable in real time and post-packet capture.

- Contributions must support solutions that are effective for both security and troubleshooting purposes.

- Contributions must support solutions that are widely available and supported in mainstream commercial products and services.

- The baseline criteria apply across the full range of scenarios described in the project description, but some

characteristics are more relevant to different categories of solutions than others. Specific characteristics relevant to different classes of solutions include:

- For solutions that achieve visibility through endpoint mechanisms (e.g., logging) or network architectures (middle boxes, overlays, or mesh service architectures), components need to support demonstration of scalability, ease of deployment, and reliable and timely access to information. For example, scalability and reliable access to historical information would be an area of interest for centralized logging solutions.

- For solutions that achieve visibility through key management mechanisms that share keys to facilitate TLS decryption, components need to support demonstration that security of keys and data against misuse or compromise and assurance that recorded traffic is not indefinitely at risk of compromise. Specifically, components would need to support demonstration that (1) the security of systems and procedures used to transmit, store, provide access to, and use the keys, and (2) mechanisms that ensure comprehensive deletion of decryption keys when established temporal or data protection limits are met.

- For solutions that achieve visibility through analysis of encrypted data, components would need to support demonstrating the capabilities and limitations of these emerging tools with respect to each of the four scenarios.

- For solutions that rely on alternative network security protocols, components would need to support demonstrating scalability, usability, and ease of deployment. If the solution also includes key management mechanisms to share keys for decryption, the properties identified above would need to be demonstrated.

- For all cases, support for demonstration of management, operational, and technical security controls that compensate and mitigate any potential new risks that may be introduced into the environment will be required.

In their letters of interest, responding organizations need to acknowledge the importance of and commit to provide:

- Access for all participants' project teams to component interfaces and the organization's experts necessary to make functional connections among security platform components.

- Support for development and demonstration of the *Addressing Visibility Challenges with TLS 1.3* project will be conducted in a manner consistent with the most recent version of the following standards and

guidance: FIPS 200, SP 800–37, SP 800–52, SP 800–53, SP 800–63, and SP 1800–16. Additional details about the *Addressing Visibility Challenges with TLS 1.3* project are available at <https://www.nccoe.nist.gov/projects/building-blocks/applied-cryptography/addressing-visibility-challenges-tls-13>.

NIST cannot guarantee that all of the products proposed by respondents will be used in the demonstration. Each prospective participant will be expected to work collaboratively with NIST staff and other project participants under the terms of the consortium CRADA in the development of the *Addressing Visibility Challenges with TLS 1.3* project. Prospective participants' contribution to the collaborative effort will include assistance in establishing the necessary interface functionality, connection and set-up capabilities and procedures, demonstration harnesses, environmental and safety conditions for use, integrated platform user instructions, and demonstration plans and scripts necessary to demonstrate the desired capabilities. Each participant will train NIST personnel, as necessary, to operate its product in capability demonstrations. Following successful demonstrations, NIST will publish a description of the security platform and its performance characteristics sufficient to permit other organizations to develop and deploy security platforms that meet the security objectives of the *Addressing Visibility Challenges with TLS 1.3* project. These descriptions will be public information.

Under the terms of the consortium CRADA, NIST will support development of interfaces among participants' products by providing IT infrastructure, laboratory facilities, office facilities, collaboration facilities, and staff support to component composition, security platform documentation, and demonstration activities.

The dates of the demonstration of the *Addressing Visibility Challenges with TLS 1.3* project capability will be announced on the NCCoE website at least two weeks in advance at <https://nccoe.nist.gov/>. The expected outcome will demonstrate how the components of the solutions that address *Visibility Challenges with TLS 1.3* can provide security capabilities to mitigate identified risks and meet industry sectors' compliance requirements. Participating organizations will gain from the knowledge that their products are interoperable with other participants' offerings.

For additional information on the NCCoE governance, business processes, and NCCoE operational structure, visit

the NCCoE website <https://nccoe.nist.gov/>.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2021-20907 Filed 9-24-21; 8:45 am]

BILLING CODE 3510-13-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB445]

Nominations for the 2022–2025 General Advisory Committee and the Scientific Advisory Subcommittee to the United States Delegation to the Inter-American Tropical Tuna Commission

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

ACTION: Notice; request for nominations.

SUMMARY: National Marine Fisheries Service, on behalf of the Secretary of Commerce, is seeking nominations for the General Advisory Committee (GAC) to the U.S. delegation to the Inter-American Tropical Tuna Commission (IATTC or Commission), as well as to a Scientific Advisory Subcommittee (SAS) of the GAC. The purpose of the GAC and its SAS is to provide public input and advice to the U.S. delegation to aid in the formulation of policy and positions for meetings of the IATTC and its subsidiary bodies. The SAS shall also function as the National Scientific Advisory Committee provided for in the Agreement on the International Dolphin Conservation Program.

DATES: Nominations must be received no later than November 29, 2021.

ADDRESSES: Nominations should be directed to Barry Thom, Regional Administrator, NMFS West Coast Region, and may be submitted by any of the following means:

- Email *RegionalAdministrator.WCRHMS@noaa.gov* with the subject line: “General Advisory Committee and Scientific Advisory Subcommittee nominations”

FOR FURTHER INFORMATION CONTACT: William Stahnke, West Coast Region, NMFS, at william.stahnke@noaa.gov, or at (562) 980-4088.

SUPPLEMENTARY INFORMATION:

General Advisory Committee

The Tuna Conventions Act (TCA) provides that the Secretary of Commerce, in consultation with the

Secretary of State, shall appoint a “General Advisory Committee” to advise the U.S. delegation to the IATTC. The GAC shall be composed of no more than 25 individuals who shall be representative of the various groups concerned with the fisheries covered by the IATTC, including non-governmental conservation organizations, providing an equitable balance among such groups to the maximum extent practicable. Members of the GAC shall be invited to attend all non-executive meetings of the U.S. delegation to the IATTC and at such meetings shall be given the opportunity to examine and be heard on all proposed programs of investigation, reports, recommendations, and regulations of the Commission.

The Chair of the Pacific Fishery Management Council’s (Pacific Council) Advisory Subpanel for Highly Migratory Fisheries and the Chair of the Western Pacific Fishery Management Council’s (Western Pacific Council) Advisory Committee shall be ex-officio members of the GAC by virtue of their positions advising those Councils. GAC members will be eligible to participate as members of the U.S. delegation to the Commission and its working groups to the extent that the Commission rules and space for delegations allow.

Meetings of the GAC, except when in executive session, shall be open to the public, and prior notice of meetings shall be made public in timely fashion. In accordance with Public Law 114–81, the GAC shall not be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

Individuals appointed to serve as a member of the GAC shall serve without pay. While away from their homes or regular places of business to attend meetings of the GAC, they shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently by the Federal Government are allowed expenses under 5 U.S.C. 5703. In addition, individuals appointed to serve as a member of the GAC shall not be considered Federal employees except for the purposes of injury compensation or tort.

Scientific Advisory Subcommittee

The TCA also provides that the Secretary of Commerce, in consultation with the Secretary of State, shall appoint persons to serve on the subcommittee of the GAC, referred to here as the “Scientific Advisory Subcommittee”. The SAS shall be composed of no fewer than 5 and no more than 15 qualified scientists with balanced representation from the public

and private sectors, including non-governmental conservation organizations. In determining whether a person is a qualified scientist the Secretary may consider, among other things, advanced degrees and/or publications in fields such as fisheries or marine science.

National Scientific Advisory Committee

The SAS shall also function as the National Scientific Advisory Committee which is required to be established pursuant to Article XI of the Agreement on the International Dolphin Conservation Program (AIDCP). In this regard, the SAS shall perform the functions of the National Scientific Advisory Committee as specified in Annex VI of the AIDCP. These functions include, but are not limited to:

(1) Receiving and reviewing relevant data, including data provided to NMFS by IATTC staff;

(2) Advising and recommending measures and actions to the U.S. Government that should be undertaken to conserve and manage stocks of living marine resources in the eastern Pacific Ocean;

(3) Making recommendations to the U.S. Government regarding research needs related to the eastern Pacific Ocean tuna purse seine fishery;

(4) Promoting the regular and timely full exchange of data among the AIDCP Parties on a variety of matters related to the implementation of the AIDCP; and

(5) Consulting with other experts, as necessary, in order to achieve the objectives of the AIDCP.

Members of the SAS/National Scientific Advisory Committee shall receive no compensation for their service.

General Provisions

Each member of the GAC shall be appointed for a term of three years, starting from the date of the appointment, and may be reappointed. The Secretary of Commerce and the Secretary of State shall provide the GAC with relevant information concerning fisheries and international fishery agreements. The Secretary of Commerce shall provide to the GAC such administrative and technical support services that are necessary for its effective functioning in a timely manner.

Procedures for Submitting Applications

Applications for the GAC and the SAS/National Scientific Advisory Committee should be submitted to NMFS West Coast Region (see **ADDRESSES**). This request for applications is for first time nominees,

current members whose appointments will end in April 2022, and previous members. Self-nomination applications are acceptable. Applications should include all of the following information:

(1) Full name, address (home and business, if different), telephone, and email address of nominee;

(2) Specification about whether the application is for the GAC or the SAS/ National Scientific Advisory Committee or both;

(3) Nominee's organization(s) or professional affiliation(s) serving as the basis for the nomination;

(4) Background statement describing the nominee's qualifications and experience, especially as related to fisheries for tuna and tuna-like species in the eastern Pacific Ocean or other factors relevant to the implementation of the Convention Establishing the IATTC or the AIDCP. Applications to the SAS should highlight advanced degrees and academic publications; and

(5) A written statement from the nominee of intent to participate actively and in good faith in the meetings and activities of either the GAC or the SAS/ National Scientific Advisory Committee, or both.

Applicants who submitted material in response to the **Federal Register** notice published by NMFS on October 30, 2018 (83 FR 54573), or prior, should resubmit their applications pursuant to this notice.

Authority: 16 U.S.C. 951 *et seq.*

Dated: September 21, 2021.

Jennifer M. Wallace,

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

[FR Doc. 2021-20803 Filed 9-24-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB339]

Deepwater Horizon Oil Spill Regionwide Trustee Implementation Group Final Restoration Plan and Environmental Assessment 1: Birds, Marine Mammals, Oysters, and Sea Turtles and Finding of No Significant Impact

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

ACTION: Notice of availability.

SUMMARY: In accordance with the Oil Pollution Act of 1990 (OPA), the National Environmental Policy Act

(NEPA), and a Consent Decree with BP Exploration & Production Inc. (BP), the *Deepwater Horizon* (DWH) Federal natural resource trustee agencies for the Regionwide Trustee Implementation Group (Regionwide TIG) prepared the Final Restoration Plan and Environmental Assessment 1: Birds, Marine Mammals, Oysters, and Sea Turtles (RP/EA), and Finding of No Significant Impact. In the RP/EA, the Regionwide TIG selected projects to help restore living coastal and marine resources injured as a result of the DWH oil spill in the Regionwide Restoration Area under the "Birds", Marine Mammals", "Oysters", and "Sea Turtles" restoration types described in the Final Programmatic Damage Assessment Restoration Plan/ Programmatic Environmental Impact Statement. The total cost to implement the Regionwide TIG's eleven selected projects is approximately \$99.6 million.

ADDRESSES: *Obtaining Documents:* You may access the RP/EA from the Regionwide TIG website at: <http://www.gulfspillrestoration.noaa.gov/restoration-areas/regionwide>.

Alternatively, you may request a CD of the RP/EA (see **FOR FURTHER INFORMATION CONTACT**). Copies are also available for review at the locations listed below (see **SUPPLEMENTARY INFORMATION**).

FOR FURTHER INFORMATION CONTACT: National Oceanic and Atmospheric Administration—Jamie Schubert, NOAA Restoration Center, (310) 427-8711, regionwide.tig@noaa.gov.

SUPPLEMENTARY INFORMATION:

Introduction

On April 20, 2010, the DWH mobile drilling unit exploded, causing a massive release of oil from the BP Exploration and Production Inc. (BP) Macondo well. The explosion and oil spill led to loss of life and extensive natural resource injuries. Oil spread from the deep ocean to surface and nearshore environments across the Gulf of Mexico, from Texas to Florida. Extensive response actions were undertaken to reduce harm to people and the environment. However, many of these response actions had collateral impacts on the environment and on natural resource services.

The DWH Federal and state natural resource trustees (DWH Trustees) conducted the natural resource damage assessment for the DWH oil spill under OPA (33 U.S.C. 2701 *et seq.*). Pursuant to OPA, Federal and state agencies act as trustees on behalf of the public to assess natural resource injuries and losses and to determine the actions

required to compensate the public for those injuries and losses. OPA further instructs the designated trustees to develop and implement a plan for the restoration, rehabilitation, replacement, or acquisition of the equivalent of the injured natural resources under their trusteeship, including the loss of use and services from those resources from the time of injury until the time of restoration to baseline (the resource quality and conditions that would exist if the spill had not occurred) is complete.

The DWH Trustees are:

- U.S. Department of the Interior (DOI), as represented by the National Park Service, U.S. Fish and Wildlife Service, and Bureau of Land Management;
- National Oceanic and Atmospheric Administration (NOAA), on behalf of the U.S. Department of Commerce;
- U.S. Department of Agriculture (USDA);
- U.S. Environmental Protection Agency (EPA);
- State of Louisiana Coastal Protection and Restoration Authority (CPRA), Oil Spill Coordinator's Office, Department of Environmental Quality, Department of Wildlife and Fisheries, and Department of Natural Resources;
- State of Mississippi Department of Environmental Quality;
- State of Alabama Department of Conservation and Natural Resources and Geological Survey of Alabama;
- State of Florida Department of Environmental Protection and Fish and Wildlife Conservation Commission; and
- State of Texas: Texas Parks and Wildlife Department, Texas General Land Office, and Texas Commission on Environmental Quality.

The DWH Trustees reached and finalized a settlement of their natural resource damage claims with BP in an April 4, 2016, Consent Decree approved by the United States District Court for the Eastern District of Louisiana. Pursuant to that Consent Decree, restoration projects in the Regionwide Restoration Area are selected and implemented by the Regionwide TIG. The Regionwide TIG is composed of the DWH Trustees listed above.

Background

On September 24, 2019, the Regionwide TIG posted a public notice at <http://www.gulfspillrestoration.noaa.gov> requesting new or revised natural resource restoration project ideas for the Regionwide Restoration Area. The notice stated that the Regionwide TIG was seeking project ideas for the following Restoration Types: (1) Birds, (2) Marine Mammals, (3) Oysters; and

(4) Sea Turtles. On July 1, 2020 the Regionwide TIG announced that it had initiated drafting of its first post settlement draft restoration plan including restoration projects for Birds, Marine Mammals, Oysters and Sea Turtles. Public comments received during the review period March 22 through May 6, 2021 (86 FR 15199) contributed to the completion of the RP/EA.

Overview of the Regionwide TIG RP/EA

The RP/EA is being released in accordance with OPA Natural Resource Damage Assessment regulations in the Code of Federal Regulations (CFR) at 15 CFR part 990, NEPA (42 U.S.C. 4321 *et seq.*), the Consent Decree,¹ and the Final Programmatic Damage Assessment and Restoration Plan/Programmatic Environmental Impact Statement. In the RP/EA, the Regionwide TIG analyzes 15 alternatives and selects eleven preferred alternatives for the Birds, Marine Mammals, Oysters, and Sea Turtles restoration types. The alternatives selected include the following:

Birds

- Reducing Marine Debris Impacts on Birds and Sea Turtles (joint project with Sea Turtles Restoration Type)—\$3,520,000;
- Conservation and Enhancement of Nesting and Foraging Habitat for Birds—\$22,500,000;
 - Component 1: Chandeleur Islands, LA, \$8,000,000;
 - Component 2: Pilot Town, AL, \$6,500,000;

- Component 3: San Antonio Bay Bird Island, TX \$2,500,000;
- Component 4: Matagorda Bay Bird Island (Chester Island), TX, \$2,500,000;
- Component 5: Round Island, MS, \$3,000,000;
- Bird Nesting and Foraging Area Stewardship—\$8,510,750.

Marine Mammals

- Voluntary Modifications to Commercial Shrimp Lazy Lines to Reduce Dolphin Entanglements—\$3,179,088;
- Reducing Impacts to Dolphins from Hook-and-Line Gear and Provisioning through Fishery Surveys, Social Science, and Collaboration—\$1,700,000;
- Enhance Marine Mammal Stranding Network Diagnostic Capabilities and Consistency across the Gulf of Mexico—\$2,300,000.

Oysters

- Improving Resilience for Oysters by Linking Brood Reefs and Sink Reefs (Large-scale)—\$35,819,974 (component cost breakdown is not yet defined);
 - Component 1: East Galveston Bay, TX;
 - Component 2: Biloxi Marsh, LA;
 - Component 3: Heron Bay, MS;
 - Component 4: Mid-lower Mobile Bay, AL;
 - Component 5: Suwanee Sound, FL.

Sea Turtles

- Pilot Implementation of Automatic Identification System in the GOM Inshore Shrimp Fishery to Inform Efforts to Reduce Sea Turtle Bycatch—\$2,231,124;

- Restore and Enhance Sea Turtle Nest Productivity—\$7,655,000;
- Reducing Sea Turtle Bycatch at Recreational Fishing Sites, \$3,649,360;
- Reducing Marine Debris Impacts on Birds and Sea Turtles (joint project with Birds Restoration Type)—\$3,520,000;
- Regionwide Enhancements to the Sea Turtle Stranding and Salvage Network and Enhanced Rehabilitation—\$5,050,000;
 - Component 1: Enhancing Response, Coordination, and Preparedness in the Gulf of Mexico, \$2,050,000;
 - Component 2: Texas Rehabilitation Facility, \$3,000,000.

The Regionwide TIG has examined the injuries assessed by the DWH Trustees and evaluated restoration alternatives to address the injuries. In the RP/EA, the Regionwide TIG presents to the public its plan for providing partial compensation to the public for injured natural resources and ecological services in the Regionwide Restoration Area. The selected alternatives are intended to continue the process of using DWH restoration funding to restore natural resources injured or lost as a result of the Deepwater Horizon oil spill. The total estimated cost of the projects selected is approximately \$99.6 million. Additional restoration planning for the Regionwide Restoration Area will continue.

Additional Access to Materials

You may request a CD of the RP/EA (see **FOR FURTHER INFORMATION CONTACT** above). Copies of the RP/EA are also available at the following locations:

TABLE 1—REPOSITORIES WITH COPIES OF THE RP/EA

Repository	Address	City	State	Zip
Dauphin Island Sea Laboratory, Admin Building	101 Bienville Blvd	Dauphin Island	AL	36528
Thomas B. Norton Public Library	221 W 19th Ave	Gulf Shores	AL	36542
Alabama Department of Conservation and Natural Resources, State Lands Division, Coastal Section Office.	31115 Five Rivers Blvd	Spanish Fort	AL	36527
Weeks Bay National Estuarine Research Reserve	11300 U.S. Hwy. 98	Fairhope	AL	36532
Mobile Public Library, West Regional Library	5555 Grelot Rd	Mobile	AL	36606
Franklin County Public Library	160 Hickory Dip	Eastpoint	FL	32328
Okaloosa County Library	185 Miracle Strip Pkwy. SE	Ft. Walton	FL	32548
Panama City Beach Public Library	125000 Hutchison Blvd	Panama City Beach	FL	32407
Southwest Branch Library	12248 Gulf Beach Hwy	Pensacola	FL	32507
Wakulla County Library	4330 Crawfordville Hwy	Crawfordville	FL	32327
Walton County Library, Coastal Branch	437 Greenway Trail	Santa Rosa Beach	FL	32459
Santa Rosa County Clerk of Court, County Courthouse.	6865 Caroline St	Milton	FL	32570
Bay County Public Library	898 W 11th St	Panama City	FL	32401
Gulf County Public Library	110 Library Dr	Port St. Joe	FL	32456
Jefferson R.J. Bailar Public Library	375 S Water St	Monticello	FL	32344
Taylor County Public Library	403 N Washington St	Perry	FL	32347
Dixie County Public Library	16328 SE U.S. Hwy. 19	Cross City	FL	32628
Levy County Public Library	7871 NE 90th St	Bronson	FL	32621

¹ Consent Decree among Defendant BP Exploration & Production Inc. ("BPXP"), the United States of America, and the States of Alabama,

Florida, Louisiana, Mississippi, and Texas entered in *In re: Oil Spill by the Oil Rig "Deepwater Horizon" in the Gulf of Mexico, on April 20, 2010*,

MDL No. 2179 in the United States District Court for the Eastern District of Louisiana.

TABLE 1—REPOSITORIES WITH COPIES OF THE RP/EA—Continued

Repository	Address	City	State	Zip
Homosassa Public Library	4100 S Grandmarch Ave	Homosassa	FL	34446
Land O'Lakes Branch Library	2818 Collier Pkwy	Land O' Lakes	FL	34639
Pinellas Public Library	1330 Cleveland St	Clearwater	FL	33755
Temple Terrace Public Library	202 Bullard Pkwy	Temple Terrace	FL	33617
South Manatee Branch Library	6081 26th St	West Bradenton	FL	34207
Jacaranda Public Library	4143 Woodmere Park Blvd	Venice	FL	34293
Mid County Regional Library	2050 Forrest Nelson Blvd	Port Charlotte	FL	33952
Riverdale Branch Library	2421 Buckingham Rd	Fort Myers	FL	33905
St. Tammany Parish Library	310 W 21st Ave	Covington	LA	70433
Terrebonne Parish Library	151 Library Dr	Houma	LA	70360
New Orleans Public Library, Louisiana Division	219 Loyola Ave	New Orleans	LA	70112
East Baton Rouge Parish Library	7711 Goodwood Blvd	Baton Rouge	LA	70806
Jefferson Parish Library, East Bank Regional Library	4747 W Napoleon Ave	Metairie	LA	70001
Jefferson Parish Library, West Bank Regional Library	2751 Manhattan Blvd	Harvey	LA	70058
Plaquemines Parish Library	8442 Hwy. 23	Belle Chase	LA	70037
St. Bernard Parish Library	2600 Palmisano Blvd	Chalmette	LA	70043
St. Martin Parish Library	201 Porter St	Martinville	LA	70582
Alex P. Allain Library	206 Iberia St	Franklin	LA	70538
Vermillion Parish Library	405 E St. Victor St	Abbeville	LA	70510
Lafourche Parish Public Library (formerly Martha Sowell Utley Memorial Library)	314 St. Mary St	Thibodaux	LA	70301
South Lafourche Public Library	16241 E Main St	Cut Off	LA	70345
Calcasieu Parish Public Library Central Branch	301 W Claude St	Lake Charles	LA	70605
Iberia Parish Library	445 E Main St	New Iberia	LA	70560
Mark Shirley, Louisiana State University AgCenter	1105 W Port St	Abbeville	LA	70510
Sandy Ha Nguyen, Coastal Communities Consulting	925 Behrman Hwy., Suite 15	Gretna	LA	70056
Biloxi Public Library, Local History and Genealogy Department	580 Howard Ave	Biloxi	MS	39530
West Biloxi Public Library	2047 Pass Rd	Biloxi	MS	39531
Waveland Public Library	333 Coleman Ave	Waveland	MS	39576
Vanceleave Public Library	12604 Hwy. 57	Vanceleave	MS	39565
Hancock County Library System	312 Hwy. 90	Bay St. Louis	MS	39520
Gulfport Harrison County Library	1708 25th Ave	Gulfport	MS	39501
Pass Christian Public Library	111 Hiern Ave	Pass Christian	MS	39571
Orange Grove Branch Library	12135 Old Hwy. 49	Gulfport	MS	39503
Kathleen McIlwain Public Library	2100 Library Ln	Gautier	MS	39553
Pascagoula Public Library	3214 Pascagoula St	Pascagoula	MS	39567
Ina Thompson Moss Point Library (formerly Moss Point Library)	4119 Bellview	Moss Point	MS	39563
Ocean Springs Municipal Library	525 Dewey Ave	Ocean Springs	MS	39564
Kiln Public Library	17065 Hwy. 603	Kiln	MS	39556
Margaret Sherry Memorial Library	2141 Popp's Ferry Rd	Biloxi	MS	39532
East Central Public Library	21801 Slider Rd	Moss Point	MS	39555
Jerry Lawrence Memorial Library (formerly D'Iberville Library)	10391 AutoMall Pkwy	D'Iberville	MS	39540
Mercy Housing & Human Development	1135 Ford St	Gulfport	MS	39507
Center for Environmental and Economic Justice	336 Rodenberg Ave	Biloxi	MS	39531
STEPS Coalition	11975 Seaway Rd., Ste. A240	Gulfport	MS	39503
Gulf Islands National Seashore Visitors Center	3500 Park Rd	Ocean Springs	MS	39564
Mississippi Commercial Fisheries United	6421 Beatline Road	Long Beach	MS	39560
Jack K. Williams Library, Texas A&M University at Galveston	200 Seawolf Pkwy., Bldg. 3010	Galveston	TX	77554
Port Arthur Public Library	4615 9th Ave	Port Arthur	TX	77672
Mary and Jeff Bell Library Texas A&M	6300 Ocean Dr	Corpus Christi	TX	78412
Rosenberg Library	2310 Sealy St	Galveston	TX	77550

Translation Opportunities

Vietnamese translated materials including the Executive Summary and project fact sheets are posted in the "News" section of the Regionwide TIG's website: <http://www.gulfspillrestoration.noaa.gov/restoration-areas/regionwide>.

Administrative Record

The documents comprising the Administrative Record for the RP/EA can be viewed electronically at <http://>

www.doi.gov/deepwaterhorizon/adminrecord.

Authority

The authority of this action is the Oil Pollution Act of 1990 (33 U.S.C. 2701 *et seq.*) and its implementing Oil Pollution Act Natural Resource Damage Assessment regulations found at 15 CFR part 990 and the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*).

Dated: September 20, 2021.

Carrie Diane Robinson,

*Director, Office of Habitat Conservation,
National Marine Fisheries Service.*

[FR Doc. 2021-20641 Filed 9-24-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[RTID: 0648–XB453]

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

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will meet with the Atlantic States Marine Fisheries Commission's Interstate Fisheries Management Program Policy Board.

DATES: The meeting will be held on Thursday, October 21, 2021, from 12:45 p.m. to 2:45 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar. Details on the agenda, webinar listen-in access, and meeting materials will be posted to <https://www.mafmc.org/council-events>.

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

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

SUPPLEMENTARY INFORMATION: During this meeting, the Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission's Interstate Fisheries Management Program Policy Board will review a draft framework action and addendum which considers a harvest control rule method for setting recreational bag, size, and season limits for summer flounder, scup, back sea bass, and bluefish. The Council and Policy Board will consider approval of a final range of management alternatives in the framework and draft addendum. The Policy Board will consider approving their draft addendum for public hearings. Background materials will be posted to www.mafmc.org/meetings.

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will

be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: September 22, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–20901 Filed 9–24–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**Patent and Trademark Office**

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

The United States Patent and Trademark Office (USPTO) will submit the following information collection request to the OMB for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The USPTO invites comment on this information collection renewal, which helps the USPTO assess the impact of its information collection requirements and minimize the public's information collection burden. Public comments were previously requested via the **Federal Register** on April 22, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: United States Patent and Trademark Office, Department of Commerce.

Title: Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 0651–0080.

Form Numbers: None.

Type of Review: Extension and revision of a currently approved information collection.

Estimated Number of Respondents: 100,000 respondents per year.

Estimated Number of Responses: 100,000 responses per year.

Estimated Time per Response: The USPTO estimates that it will take the public approximately 10 minutes to gather the necessary information, create the document, and submit the completed information to the USPTO.

Estimated Total Annual Respondent Burden Hours: 16,667 hours.

Estimated Total Annual Non-Hour Cost Burden: \$0.

Needs and Uses: The Agency will collect, analyze, and interpret information gathered to identify strengths and weaknesses of current services. Based on feedback received, the Agency will identify changes needed to improve programs and services. The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. The USPTO is committed to hearing feedback from its customers. Responses will be assessed to identify service areas in need of improvement. This information collection covers a variety of methods used by USPTO to obtain qualitative feedback from the public.

Affected Public: Private sector; individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

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

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and entering either the title of the information collection or the OMB Control Number 0651–0080.

Further information can be obtained by:

- *Email:* InformationCollection@uspto.gov. Include “0651–0080 information request” in the subject line of the message.

- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office,

P.O. Box 1450, Alexandria, VA 22313–1450.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2021–20949 Filed 9–24–21; 8:45 am]

BILLING CODE 3510–16–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Package for Day of Service Project Collection Tool

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service (operating as AmeriCorps) is proposing to renew an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by November 26, 2021.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to AmeriCorps, Attention: Rhonda Taylor, 250 E Street SW, Washington, DC 20525.

(2) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except federal holidays.

(3) Electronically through www.regulations.gov.

Comments submitted in response to this notice may be made available to the public through regulations.gov. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public,

notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Rhonda Taylor at 202–606–6721 or by email to rtaylor@cns.gov.

SUPPLEMENTARY INFORMATION:

Title of Collection: Day of Service Project Collection Tool.

OMB Control Number: 3045–0122.

Type of Review: Renewal.

Respondents/Affected Public: Individuals and Households, Businesses and Organizations.

Total Estimated Number of Annual Responses: 100,000.

Total Estimated Number of Annual Burden Hours: 17,000.

Abstract: AmeriCorps is soliciting comments concerning the proposed renewal of its Day of Service project promotion tool. Organizers of volunteer events will be able to register their projects. This group includes national service grantees, corporations, volunteer organizations, government entities, and individuals. AmeriCorps wants to help promote activities across the country and also to assess impact of the agency's initiatives. Information provided is purely voluntary and will not be used for any grant or funding support. AmeriCorps also seeks to continue using the currently approved information collection until the revised information collection is approved by OMB. The currently approved information collection is due to expire on 12/31/2021.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of

collecting, validating, and verifying information, processing, and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on regulations.gov.

Dated: September 20, 2021.

Rhonda Taylor,

Director of Partnerships and Program Engagement.

[FR Doc. 2021–20814 Filed 9–24–21; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–OS–0070]

Submission for OMB Review; Comment Request

AGENCY: Office of the Chief Information Officer, Department of Defense (DoD).

ACTION: 30-day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, 571–372–7574, or whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Basic Employee and Security Tracking Systems (BEAST); OMB Control Number 0704–0507.

Type of Request: Extension.

Number of Respondents: 150.

Responses per Respondent: 1.

Annual Responses: 150.

Average Burden per Response: 0.25 hours (15 minutes).

Annual Burden Hours: 37.5.

Needs and Uses: The information collection requirement is necessary to

obtain, track, and record the personnel security data, training information, and travel history within the White House Military Office (WHMO) and White House Communications Agency (WHCA).

Affected Public: Individuals or Households.

Frequency: On Occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

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

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to

Ms. Duncan at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: September 21, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021-20932 Filed 9-24-21; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Revised Non-Foreign Overseas Per Diem Rates

AGENCY: Defense Human Resources Activity, Department of Defense (DoD).

ACTION: Notice of revised per diem rates in non-foreign areas outside the continental U.S.

SUMMARY: Defense Human Resources Activity (DHRA) publishes this Civilian Personnel Per Diem Bulletin Number 318. Bulletin Number 318 lists current per diem rates prescribed for reimbursement of subsistence expenses while on official Government travel to Alaska, Hawaii, the Commonwealth of Puerto Rico, and the possessions of the United States. The Fiscal Year (FY) 2021 lodging rate review resulted in lodging rate changes in certain locations.

DATES: The updated rates take effect October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. David J. Maly, phone: 571-372-1316; email: david.j.maly.civ@mail.mil.

SUPPLEMENTARY INFORMATION: This document notifies the public of revisions in per diem rates prescribed by the Per Diem, Travel and Transportation Allowance Committee for travel to non-foreign areas outside the continental United States. The FY 2021 lodging rate review for Alaska resulted in lodging rate changes in certain locations. Bulletin Number 318 is published in the **Federal Register** to ensure that Government travelers outside the Department of Defense are notified of revisions to the current reimbursement rates.

If you believe the lodging, meal or incidental allowance rate for a locality listed in the following table is insufficient, you may request a rate review for that location. For more information about how to request a review, please see the Defense Travel Management Office's Per Diem Rate Review Frequently Asked Questions (FAQ) page at <https://www.defense.travel.dod.mil/site/faqraterev.cfm>.

Dated: September 22, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

State or territory	Locality	Season start	Season end	Lodging	M&IE	Total per diem	Effective date
ALASKA	[OTHER]	01/01	12/31	171	113	284	10/01/2021
ALASKA	ADAK	01/01	12/31	171	113	284	10/01/2021
ALASKA	ANCHORAGE	01/01	12/31	229	125	354	10/01/2021
ALASKA	BARROW	06/01	08/31	326	129	455	10/01/2021
ALASKA	BARROW	09/01	05/31	252	129	381	10/01/2021
ALASKA	BARTER ISLAND LRRS	01/01	12/31	171	113	284	10/01/2021
ALASKA	BETHEL	01/01	12/31	219	101	320	10/01/2021
ALASKA	BETTLES	01/01	12/31	171	113	* 284	10/01/2021
ALASKA	CAPE LISBURNE LRRS	01/01	12/31	171	113	284	10/01/2021
ALASKA	CAPE NEWENHAM LRRS	01/01	12/31	171	113	284	10/01/2021
ALASKA	CAPE ROMANZOF LRRS	01/01	12/31	171	113	284	10/01/2021
ALASKA	CLEAR AB	01/01	12/31	171	113	284	10/01/2021
ALASKA	COLD BAY	01/01	12/31	171	113	284	10/01/2021
ALASKA	COLD BAY LRRS	01/01	12/31	171	113	284	10/01/2021
ALASKA	COLDFOOT	01/01	12/31	219	93	312	10/01/2021
ALASKA	COPPER CENTER	01/01	12/31	171	115	286	10/01/2021
ALASKA	CORDOVA	03/01	10/31	174	106	280	10/01/2021
ALASKA	CORDOVA	11/01	02/28	150	106	256	10/01/2021
ALASKA	CRAIG	05/01	09/30	139	94	233	10/01/2021
ALASKA	CRAIG	10/01	04/30	109	94	203	10/01/2021
ALASKA	DEADHORSE	01/01	12/31	171	113	* 284	10/01/2021
ALASKA	DELTA JUNCTION	01/01	12/31	171	101	272	10/01/2021
ALASKA	DENALI NATIONAL PARK	05/01	10/14	164	98	262	10/01/2021
ALASKA	DENALI NATIONAL PARK	10/15	04/30	99	98	197	10/01/2021
ALASKA	DILLINGHAM	05/01	09/30	320	113	433	10/01/2021
ALASKA	DILLINGHAM	10/01	04/30	298	113	411	10/01/2021
ALASKA	DUTCH HARBOR-UNALASKA	01/01	12/31	171	129	300	10/01/2021
ALASKA	EARECKSON AIR STATION	01/01	12/31	146	74	220	10/01/2021
ALASKA	EIELSON AFB	05/16	09/30	154	100	254	10/01/2021
ALASKA	EIELSON AFB	10/01	05/15	79	100	179	10/01/2021
ALASKA	ELFIN COVE	01/01	12/31	171	113	284	10/01/2021
ALASKA	ELMENDORF AFB	01/01	12/31	229	125	354	10/01/2021
ALASKA	FAIRBANKS	05/16	09/30	154	100	254	10/01/2021
ALASKA	FAIRBANKS	10/01	05/15	79	100	179	10/01/2021
ALASKA	FORT YUKON LRRS	01/01	12/31	171	113	284	10/01/2021
ALASKA	FT. GREELY	01/01	12/31	171	101	272	10/01/2021
ALASKA	FT. RICHARDSON	01/01	12/31	229	125	354	10/01/2021

State or territory	Locality	Season start	Season end	Lodging	M&IE	Total per diem	Effective date
ALASKA	FT. WAINWRIGHT	05/16	09/30	154	100	254	10/01/2021
ALASKA	FT. WAINWRIGHT	10/01	05/15	79	100	179	10/01/2021
ALASKA	GAMBELL	01/01	12/31	171	113	284	10/01/2021
ALASKA	GLENNALLEN	01/01	12/31	171	113	284	10/01/2021
ALASKA	HAINES	01/01	12/31	159	113	272	10/01/2021
ALASKA	HEALY	05/01	10/14	164	98	262	10/01/2021
ALASKA	HEALY	10/15	04/30	99	98	197	10/01/2021
ALASKA	HOMER	05/01	09/30	189	124	313	10/01/2021
ALASKA	HOMER	10/01	04/30	129	124	253	10/01/2021
ALASKA	JB ELMENDORF-RICHARDSON	01/01	12/31	229	125	354	10/01/2021
ALASKA	JUNEAU	02/01	09/30	249	118	367	10/01/2021
ALASKA	JUNEAU	10/01	01/31	189	118	307	10/01/2021
ALASKA	KAKTOVIK	01/01	12/31	171	113	* 284	10/01/2021
ALASKA	KAVIK CAMP	01/01	12/31	171	113	* 284	10/01/2021
ALASKA	KENAI-SOLDOTNA	05/01	09/30	151	113	264	10/01/2021
ALASKA	KENAI-SOLDOTNA	10/01	04/30	104	113	217	10/01/2021
ALASKA	KENNICOTT	01/01	12/31	171	85	256	10/01/2021
ALASKA	KETCHIKAN	05/01	10/31	250	118	368	10/01/2021
ALASKA	KETCHIKAN	11/01	04/30	140	118	258	10/01/2021
ALASKA	KING SALMON	01/01	12/31	171	89	264	10/01/2021
ALASKA	KING SALMON LRRS	01/01	12/31	171	113	288	10/01/2021
ALASKA	KLAWOCK	05/01	09/30	139	94	233	10/01/2021
ALASKA	KLAWOCK	10/01	04/30	109	94	203	10/01/2021
ALASKA	KODIAK	05/01	09/30	207	109	316	10/01/2021
ALASKA	KODIAK	10/01	04/30	123	109	232	10/01/2021
ALASKA	KOTZEBUE	01/01	12/31	171	121	296	10/01/2021
ALASKA	KULIS AGS	01/01	12/31	229	125	354	10/01/2021
ALASKA	MCCARTHY	01/01	12/31	171	85	256	10/01/2021
ALASKA	MCGRATH	01/01	12/31	171	113	* 284	10/01/2021
ALASKA	MURPHY DOME	05/16	09/30	154	100	254	10/01/2021
ALASKA	MURPHY DOME	10/01	05/15	79	100	179	10/01/2021
ALASKA	NOME	01/01	12/31	200	118	318	10/01/2021
ALASKA	NOSC ANCHORAGE	01/01	12/31	229	125	354	10/01/2021
ALASKA	NUIQSUT	01/01	12/31	171	113	* 284	10/01/2021
ALASKA	OLIKTOK LRRS	01/01	12/31	171	113	284	10/01/2021
ALASKA	PALMER	01/01	12/31	171	117	288	10/01/2021
ALASKA	PETERSBURG	01/01	12/31	130	108	238	10/01/2021
ALASKA	POINT BARROW LRRS	01/01	12/31	171	113	284	10/01/2021
ALASKA	POINT HOPE	01/01	12/31	171	113	* 284	10/01/2021
ALASKA	POINT LONELY LRRS	01/01	12/31	171	113	284	10/01/2021
ALASKA	PORT ALEXANDER	01/01	12/31	171	113	* 284	10/01/2021
ALASKA	PORT ALSWORTH	01/01	12/31	171	113	284	10/01/2021
ALASKA	PRUDHOE BAY	01/01	12/31	171	113	* 284	10/01/2021
ALASKA	SELDOVIA	05/01	09/30	189	124	313	10/01/2021
ALASKA	SELDOVIA	10/01	04/30	129	124	253	10/01/2021
ALASKA	SEWARD	04/01	09/30	299	146	445	10/01/2021
ALASKA	SEWARD	10/01	03/31	104	146	250	10/01/2021
ALASKA	SITKA-MT. EDGE CUMBE	04/01	09/30	220	116	336	10/01/2021
ALASKA	SITKA-MT. EDGE CUMBE	10/01	03/31	189	116	305	10/01/2021
ALASKA	SKAGWAY	05/01	10/31	250	118	368	10/01/2021
ALASKA	SKAGWAY	11/01	04/30	140	118	258	10/01/2021
ALASKA	SLANA	01/01	12/31	171	113	284	10/01/2021
ALASKA	SPARREVOHN LRRS	01/01	12/31	171	113	284	10/01/2021
ALASKA	SPRUCE CAPE	05/01	09/30	207	109	316	10/01/2021
ALASKA	SPRUCE CAPE	10/01	04/30	123	109	232	10/01/2021
ALASKA	ST. GEORGE	01/01	12/31	171	113	284	10/01/2021
ALASKA	TALKEETNA	01/01	12/31	171	120	291	10/01/2021
ALASKA	TANANA	01/01	12/31	200	118	318	10/01/2021
ALASKA	TATALINA LRRS	01/01	12/31	171	113	284	10/01/2021
ALASKA	TIN CITY LRRS	01/01	12/31	171	113	284	10/01/2021
ALASKA	TOK	01/01	12/31	105	113	218	10/01/2021
ALASKA	VALDEZ	05/01	09/15	212	110	322	10/01/2021
ALASKA	VALDEZ	09/16	04/30	129	110	239	10/01/2021
ALASKA	WAINWRIGHT	01/01	12/31	275	77	352	10/01/2021
ALASKA	WASILLA	06/01	10/31	171	94	265	10/01/2021
ALASKA	WASILLA	11/01	05/31	90	94	184	10/01/2021
ALASKA	WRANGELL	05/01	10/31	250	118	368	10/01/2021
ALASKA	WRANGELL	11/01	04/30	140	118	258	10/01/2021
ALASKA	YAKUTAT	06/01	10/15	350	111	461	10/01/2021
ALASKA	YAKUTAT	10/16	05/31	150	111	261	10/01/2021
AMERICAN SAMOA	AMERICAN SAMOA	01/01	12/31	139	86	225	07/01/2019
AMERICAN SAMOA	PAGO PAGO	01/01	12/31	139	86	225	07/01/2019
GUAM	GUAM (INCL ALL MIL INSTAL)	01/01	12/31	159	96	255	04/01/2021
GUAM	JOINT REGION MARIANAS (ANDERSEN)	01/01	12/31	159	96	255	04/01/2021
GUAM	JOINT REGION MARIANAS (NAVAL BASE)	01/01	12/31	159	96	255	04/01/2021
GUAM	TAMUNING	01/01	12/31	159	96	255	04/01/2021
HAWAII	[OTHER]	01/01	12/31	218	149	367	01/01/2021
HAWAII	CAMP H M SMITH	01/01	12/31	177	149	326	01/01/2021
HAWAII	CNI NAVMAG PEARL HARBOR-HICKAM	01/01	12/31	177	149	326	01/01/2021
HAWAII	FT. DERUSSEY	01/01	12/31	177	149	326	01/01/2021

State or territory	Locality	Season start	Season end	Lodging	M&IE	Total per diem	Effective date
HAWAII	FT. SHAFTER	01/01	12/31	177	149	326	01/01/2021
HAWAII	HICKAM AFB	01/01	12/31	177	149	326	01/01/2021
HAWAII	HONOLULU	01/01	12/31	177	149	326	01/01/2021
HAWAII	ISLE OF HAWAII: HILO	01/01	12/31	199	120	319	01/01/2021
HAWAII	ISLE OF HAWAII: LOCATIONS OTHER THAN HILO.	01/01	12/31	218	156	374	01/01/2021
HAWAII	ISLE OF KAUAI	01/01	12/31	325	141	466	01/01/2021
HAWAII	ISLE OF LANAI	01/01	12/31	218	134	352	01/01/2021
HAWAII	ISLE OF MAUI	01/01	12/31	304	150	454	01/01/2021
HAWAII	ISLE OF MOLOKAI	01/01	12/31	218	106	324	01/01/2021
HAWAII	ISLE OF OAHU	01/01	12/31	177	149	326	01/01/2021
HAWAII	JB PEARL HARBOR-HICKAM	01/01	12/31	177	149	326	01/01/2021
HAWAII	KAPOLEI	01/01	12/31	177	149	326	01/01/2021
HAWAII	KEKAHA PACIFIC MISSILE RANGE FAC.	01/01	12/31	325	141	466	01/01/2021
HAWAII	KILAUEA MILITARY CAMP	01/01	12/31	199	120	319	01/01/2021
HAWAII	LIHUE	01/01	12/31	325	141	466	01/01/2021
HAWAII	MCB HAWAII	01/01	12/31	177	149	326	01/01/2021
HAWAII	NCTAMS PAC WAHIAWA	01/01	12/31	177	149	326	01/01/2021
HAWAII	NOSC PEARL HARBOR	01/01	12/31	177	149	326	01/01/2021
HAWAII	PEARL HARBOR	01/01	12/31	177	149	326	01/01/2021
HAWAII	PMRF BARKING SANDS	01/01	12/31	325	141	466	01/01/2021
HAWAII	SCHOFIELD BARRACKS	01/01	12/31	177	149	326	01/01/2021
HAWAII	TRIPLER ARMY MEDICAL CENTER.	01/01	12/31	177	149	326	01/01/2021
HAWAII	WHEELER ARMY AIRFIELD	01/01	12/31	177	149	326	01/01/2021
MIDWAY ISLANDS	MIDWAY ISLANDS	01/01	12/31	125	81	206	01/01/2021
NORTHERN MARIANA ISLANDS	[OTHER]	01/01	12/31	80	113	182	04/01/2021
NORTHERN MARIANA ISLANDS	ROTA	01/01	12/31	130	114	244	04/01/2021
NORTHERN MARIANA ISLANDS	SAIPAN	01/01	12/31	161	113	274	04/01/2021
NORTHERN MARIANA ISLANDS	TINIAN	01/01	12/31	80	93	162	04/01/2021
PUERTO RICO	[OTHER]	01/01	12/31	159	100	259	05/01/2021
PUERTO RICO	AGUADILLA	01/01	12/31	149	90	239	05/01/2021
PUERTO RICO	BAYAMON	12/01	05/31	195	115	310	05/01/2021
PUERTO RICO	BAYAMON	06/01	11/30	167	115	282	05/01/2021
PUERTO RICO	CAROLINA	12/01	05/31	195	115	310	05/01/2021
PUERTO RICO	CAROLINA	06/01	11/30	167	115	282	05/01/2021
PUERTO RICO	CEIBA	01/01	12/31	159	110	269	05/01/2021
PUERTO RICO	CULEBRA	01/01	12/31	159	105	264	05/01/2021
PUERTO RICO	FAJARDO [INCL ROOSEVELT RDS NAVSTAT].	01/01	12/31	159	110	269	05/01/2021
PUERTO RICO	FT. BUCHANAN [INCL GSA SVC CTR, GUAYNABO].	12/01	05/31	195	115	310	05/01/2021
PUERTO RICO	FT. BUCHANAN [INCL GSA SVC CTR, GUAYNABO].	06/01	11/30	167	115	282	05/01/2021
PUERTO RICO	HUMACAO	01/01	12/31	159	110	269	05/01/2021
PUERTO RICO	LUIS MUNOZ MARIN IAP AGS	12/01	05/31	195	115	310	05/01/2021
PUERTO RICO	LUIS MUNOZ MARIN IAP AGS	06/01	11/30	167	115	282	05/01/2021
PUERTO RICO	LUQUILLO	01/01	12/31	159	110	269	05/01/2021
PUERTO RICO	MAYAGUEZ	01/01	12/31	109	94	203	05/01/2021
PUERTO RICO	PONCE	01/01	12/31	149	130	279	05/01/2021
PUERTO RICO	RIO GRANDE	01/01	12/31	169	85	254	05/01/2021
PUERTO RICO	SABANA SECA [INCL ALL MILITARY].	12/01	05/31	195	115	310	05/01/2021
PUERTO RICO	SABANA SECA [INCL ALL MILITARY].	06/01	11/30	167	115	282	05/01/2021
PUERTO RICO	SAN JUAN & NAV RES STA	12/01	05/31	195	115	310	05/01/2021
PUERTO RICO	SAN JUAN & NAV RES STA	06/01	11/30	167	115	282	05/01/2021
PUERTO RICO	VIEQUES	01/01	12/31	159	94	253	05/01/2021
VIRGIN ISLANDS (U.S.)	ST. CROIX	12/15	04/14	299	120	419	04/01/2021
VIRGIN ISLANDS (U.S.)	ST. CROIX	04/15	12/14	247	120	367	04/01/2021
VIRGIN ISLANDS (U.S.)	ST. JOHN	12/04	04/30	230	123	353	04/01/2021
VIRGIN ISLANDS (U.S.)	ST. JOHN	05/01	12/03	170	123	293	04/01/2021
VIRGIN ISLANDS (U.S.)	ST. THOMAS	04/15	12/15	249	118	367	04/01/2021
VIRGIN ISLANDS (U.S.)	ST. THOMAS	12/16	04/14	339	118	457	04/01/2021
WAKE ISLAND	WAKE ISLAND	01/01	12/31	129	70	199	01/01/2021

* Where meals are included in the lodging rate, a traveler is only allowed a meal rate on the first and last day of travel.

[FR Doc. 2021-20948 Filed 9-24-21; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE**Office of the Secretary****[Docket ID: DoD–2021–OS–0072]****Submission for OMB Review;
Comment Request**

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: 30-day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Angela Duncan, 571–372–7574, or whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Transitional Compensation for Abused Dependents (TCAD); DD Form 2698; OMB Control Number 0704–0578.

Type of Request: Regular.
Number of Respondents: 500.
Responses per Respondent: 1.
Annual Responses: 500.
Average Burden per Response: 20 minutes.

Annual Burden Hours: 166.7 hours.
Needs and Uses: The information

collection requirement is necessary to establish eligibility, determine the number of payments, determine the number of dependents, determine the amount of compensation, and direct payment to the abused dependent(s). Respondents are abused dependents or former dependents, or legal representatives of abused dependents or former dependents, of service members who are convicted or administratively separated from military service due to a dependent abuse offense. In order to receive the benefit, the recipient must complete the required information in DD Form 2698.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

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

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: September 21, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–20936 Filed 9–24–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE**Office of the Secretary****[Docket ID: DoD–2021–OS–0053]****Submission for OMB Review;
Comment Request**

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Angela Duncan, 571–372–7574, or

whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: QuickCompass of Sexual Assault Prevention and Response Personnel (QSAPR), OMB Control Number 0704–0603.

Type of Request: Extension.

Number of Respondents: 5,000.

Responses per Respondent: 1.

Annual Responses: 5,000.

Average Burden per Response: 20 minutes.

Annual Burden Hours: 1,667 hours.

Needs and Uses: The QuickCompass of Sexual Assault Prevention and Response Personnel (QSAPR) assesses perceived professional or other reprisal or retaliation; access to sufficient physical and mental health services as a result of the nature of their work; access to installation and unit commanders; access to victims and alleged offender's immediate commander; responsiveness of commanders to Sexual Assault Response Coordinators (SARCs); support and services provided to sexual assault victims; understanding of others of the process and their willingness to assist; adequacy of training received by SARCs and Sexual Assault Prevention and Response (SAPR) VAs to effectively perform their duties; and other factors affecting the ability of SARCs and SAPR VAs to perform their duties. In addition, the results of the survey will assess progress, identify shortfalls, and revise policies and programs as needed. The FY21 NDAA requires that not later than June 30, 2021 the Secretary of Defense (SECDEF) survey SARCs and SAPR VAs on their ability to perform duties. SECDEF is required to submit a report of the survey results and actions to be taken as a result of the survey to the Senate and House Committees on Armed Services. In order to be able to meet reporting requirements for DoD leadership, the Military Services, and Congress, the survey needs to be completed by May 2021 to be able to present results to leadership by the end of 2021. That will also allow the results to be shared with the Department and Congress in the DoD SAPRO Annual Report as they have been in previous cycles. Data will be aggregated and reported triennially in perpetuity. Ultimately, the study will provide a report to Congress and all of the data, programs, and computational details necessary for replication and peer review.

Affected Public: Individuals or households.

Frequency: Every 3 years.

Respondent's Obligation: Voluntary.
OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

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

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: September 21, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021-20941 Filed 9-24-21; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2021-OS-0059]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, 571-372-7574, or

whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated form; and OMB Number: Service Academy Gender Relations Survey; OMB Control Number 0704-SAGR.

Type of Request: Regular.

Number of Respondents: 10,000.

Responses per Respondent: 1.

Annual Responses: 10,000.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 5,000 hours.

Needs and Uses: The legal requirements for the Service Academy Gender Relations (SAGR) surveys can be found in the following:

- 10 United States Code (U.S.C.), Section 4361, as amended by John Warner National Defense Authorization Act NDAA for Fiscal Year (FY) 2007, Section 532
- 10 United States Code (U.S.C.), Section 481
- Department of Defense Instruction (DoDI) 6495.02

These legal requirements mandate that the SAGR solicit information relating to sexual assault, sexual harassment, and gender discrimination in the Military Service Academies (MSAs), as well as the climate at the MSAs and social perspectives. MSAs include the U.S. Military Service Academy (USMA), the U.S. Naval Academy (USNA), and U.S. Air Force Academy (USAFA). The requirements state that the assessment cycle consists of surveys and focus groups during alternate years. They also give the Department authority to conduct such surveys under the guidance of the Under Secretary of Defense for Personnel and Readiness (USD(P&R)). The U.S. Coast Guard Academy (USCGA), the only Federal Military Academy within the Department of Homeland Security (DHS), is not required to participate in the assessments codified by U.S.C. 10. However, USCGA officials requested the Coast Guard be included, beginning in 2008, in order to evaluate and improve their programs addressing sexual assault and sexual harassment. Similarly, the U.S. Merchant Marine Academy (USMMA), under the Department of Transportation (DOT), requested their inclusion beginning in 2012. USCGA and USMMA will continue to participate in the assessments. Surveys of USCGA and USMMA are not covered under this DoD licensure and will not be mentioned further.

The Office of People Analytics (OPA) administers both web-based and paper-and-pen surveys to support the

personnel information needs of the USD(P&R). The SAGR survey expands a series of surveys that began in 2004 with the DoD Inspector General's first survey, subsequently transferred to OPA. OPA conducted the SAGR survey at the MSAs in 2005, 2006, 2008, 2010, 2012, 2014, 2016, and 2018. The 2020 administration of the survey was postponed due to the COVID-19 pandemic. The 2022 survey would be the ninth iteration of the SAGR survey. The first focus group assessment was conducted in 2007, with subsequent focus groups in 2009, 2011, 2013, 2015, 2017, 2019, and 2021. Information from the SAGR surveys will be used by DoD policy offices, the Military Departments, the MSAS, and Congress for program evaluation and, specifically, to assess and improve policies, programs, practices, and training related to gender relations at the MSAs. OPA will provide reports to DoD policy offices, each Military Department, the MSAs, the Joint Chiefs of Staff (JCS), and Congress.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

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

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: September 21, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021-20944 Filed 9-24-21; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE**Office of the Secretary****[Docket ID: DoD–2021–OS–0064]****Submission for OMB Review;
Comment Request**

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Angela Duncan, 571–372–7574, or whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Base Realignment and Closure (BRAC) Military Base Reuse Status; DD Form 2740; OMB Control Number 0790–0003.

Type of Request: Extension.
Number of Respondents: 100.
Responses per Respondent: 1.
Annual Responses: 100.
Average Burden per Response: 1 hour.
Annual Burden Hours: 100 hours.
Needs and Uses: Through the Office of Local Defense Community Cooperation (OLDCC), Department of Defense (DoD) funds are provided to communities for economic adjustment planning in response to closures and realignments of military installations. A measure of program evaluation is the monitoring of civilian job creation, and the type of redevelopment at former military installations. The respondents to the annual survey will generally be a single point of contact at the local level that is responsible for overseeing the base redevelopment effort. If this data is not collected, OLDCC will have no accurate, timely information regarding the civilian reuse of former military bases. As the administrator of the Defense Economic Adjustment Program,

OLDCC has a responsibility to encourage private sector use of lands and buildings to generate jobs as military activity diminishes, and to serve as a clearinghouse for reuse data.

Affected Public: Business or other for-profit; State, Local, or Tribal Government.

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

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

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: September 21, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–20946 Filed 9–24–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE**Department of the Navy****[Docket ID: USN–2021–HQ–0009]****Proposed Collection; Comment Request**

AGENCY: Chief of Navy Personnel, OPNAV N1, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Chief of Navy Personnel, OPNAV N1, announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have

practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by November 26, 2021.

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: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to OPNAV N1, Department of the Navy, 701 Courthouse Road, Arlington, VA, 22204, ATTN: Richard Linton, Ph.D. or call 703–604–6058.

SUPPLEMENTARY INFORMATION: *Title; Associated Form; and OMB Number:* Navy Health of the Force Survey, OMB Control Number 0703–0079.

Needs and Uses: The Navy Health of the Force Survey is a strategic level engagement survey of the Navy Active Duty population that addresses core measures relating to the health of the force and addresses emergent issues of interest to Navy leadership. The survey will provide answers to important questions for Navy leadership including: Sailor job satisfaction, retention plans, and influences to stay or leave; value of different incentives for extended sea duty; sailor well-being including quality and amount of sleep, prevalence of burnout, stress and sources of stress; sailors' commitment to the organization and sense of unit cohesion.

Affected Public: Navy Active Duty Personnel.

Annual Burden Hours: 5,417 hours.

Number of Respondents: 13,000.

Responses per Respondent: 1.

Annual Responses: 13,000.

Average Burden per Response: 25 minutes.

Frequency: Once.

Dated: September 21, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–20930 Filed 9–24–21; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0141]

Agency Information Collection Activities; Comment Request; Student Aid Internet Gateway (SAIG) Enrollment Document

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before November 26, 2021.

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–2021–SCC–0141. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the www.regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Student Aid Internet Gateway (SAIG) Enrollment Document.

OMB Control Number: 1840–0002.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 48,436.

Total Estimated Number of Annual Burden Hours: 10,015.

Abstract: This is a request for an extension without change of the approval of the Student Aid Internet Gateway (SAIG) Enrollment forms. These forms allow various Department program partners to apply to participate with the Department in electronically transmitting and receiving data regarding federal student aid programs. These documents are updated annually.

Dated: September 22, 2021.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–20857 Filed 9–24–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0142]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Endowment Excise Tax: Allocation Reduction Waiver

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before October 27, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection request by selecting “Department of Education” under “Currently Under Review,” then check “Only Show ICR for Public Comment” checkbox. Comments may also be sent to ICDocketmgr@ed.gov.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Karen Epps, 202–453–6337.

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: Endowment Excise Tax: Allocation Reduction Waiver.

OMB Control Number: 1840-0858.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 200.

Total Estimated Number of Annual Burden Hours: 200.

Abstract: In accordance with the Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (CRRSAA), Public Law 116-260, section 314(d)(6)(B), the Secretary may waive the requirements to reduce a grantee's CRRSAA allocation by 50 percent, if upon application, an institution of higher education demonstrates need (including need for additional funding for financial aid grants to students, payroll expenses, or other expenditures) for the total amount of funds such institution is allocated under section 314(a)(1) of CRRSAA. The proposed form provides institutions with the opportunity to request this waiver and collects data needed to evaluate their waiver request.

Dated: September 22, 2021.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021-20858 Filed 9-24-21; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG21-257-000.

Applicants: Drew Solar, LLC.

Description: Notice of Self-

Certification of Exempt Wholesale Generator Status of Drew Solar, LLC.

Filed Date: 9/21/21.

Accession Number: 20210921-5037.

Comment Date: 5 p.m. ET 10/12/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10-1819-028; ER10-1820-031.

Applicants: Northern States Power Company, a Wisconsin corporation, Northern States Power Company, a Minnesota corporation.

Description: Supplement to December 18, 2020 Triennial Market Power Analysis for Central Region of Northern States Power Company, a Minnesota corporation, et al.

Filed Date: 9/20/21.

Accession Number: 20210920-5183.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: ER17-1821-004.

Applicants: Panda Stonewall LLC.

Description: Refund Report: First Reactive Service Refund Report—Docket No. ER17-1821 to be effective N/A.

Filed Date: 9/21/21.

Accession Number: 20210921-5091.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: ER21-2798-001.

Applicants: Florida Power & Light Company.

Description: Tariff Amendment: Amendment to Florida Power & Light Company's Filing to Re-file MBR Tariff to be effective 9/1/2021.

Filed Date: 9/21/21.

Accession Number: 20210921-5056.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: ER21-2911-000.

Applicants: Drew Solar, LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authority to be effective 11/1/2021.

Filed Date: 9/21/21.

Accession Number: 20210921-5016.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: ER21-2912-000.

Applicants: Drew Solar-CA, LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authority to be effective 11/1/2021.

Filed Date: 9/21/21.

Accession Number: 20210921-5017.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: ER21-2913-000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2021-09-21 Transferred Frequency Response Agmt—Tucson to be effective 12/1/2021.

Filed Date: 9/21/21.

Accession Number: 20210921-5063.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: ER21-2914-000.

Applicants: Midcontinent

Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2021-09-21 Short-Term Reserve True-up Filing to be effective 12/7/2021.

Filed Date: 9/21/21.

Accession Number: 20210921-5074.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: ER21-2915-000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Service Agreement No. 393 to be effective 9/2/2021.

Filed Date: 9/21/21.

Accession Number: 20210921-5083.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: ER21-2916-000.

Applicants: Milford Wind Corridor Phase I, LLC.

Description: § 205(d) Rate Filing: Notice of Change in Category Seller Status in the SW Region to be effective 9/22/2021.

Filed Date: 9/21/21.

Accession Number: 20210921-5087.

Comment Date: 5 p.m. ET 10/12/21.

Docket Numbers: ER21-2917-000.

Applicants: Milford Wind Corridor Phase II, LLC.

Description: § 205(d) Rate Filing: Notice of Change in Category Seller Status in the SW Region to be effective 9/22/2021.

Filed Date: 9/21/21.

Accession Number: 20210921-5088.

Comment Date: 5 p.m. ET 10/12/21.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by 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: September 21, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021-20897 Filed 9-24-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. 6951–018]

Tallassee Shoals, LLC; Notice of Application Tendered for Filing With The Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

- a. *Type of Application*: New License.
- b. *Project No.*: 6951–018.
- c. *Date filed*: September 15, 2021.
- d. *Applicant*: Tallassee Shoals, LLC.
- e. *Name of Project*: Tallassee Shoals Hydroelectric Project (project).
- f. *Location*: On the Middle Oconee River, in Athens-Clarke and Jackson Counties, Georgia. The project does not occupy any federal land.
- g. *Filed Pursuant to*: Federal Power Act 16 U.S.C. 791(a)–825(r).
- h. *Applicant Contact*: Walter Puryear, Tallassee Shoals, LLC, 2399 Tallassee Road, Athens, Georgia 30607; Phone at (706) 540–7621, or email at wpuryear@bellsouth.net.
- i. *FERC Contact*: Michael Spencer at (202) 502–6093, or michael.spencer@ferc.gov.
- j. *Cooperating agencies*: Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).
- k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.
- l. With this notice, we are designating Tallassee Shoals, LLC as the Commission's non-federal

representative for carrying out informal consultation pursuant to section 7 of the Endangered Species Act; and consultation pursuant to section 106 of the National Historic Preservation Act.

m. Deadline for filing additional study requests and requests for cooperating agency status: November 14, 2021.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at <https://ferconline.ferc.gov/FEROnline.aspx>. For assistance, please contact FERC Online Support at FEROnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Tallassee Shoals Hydroelectric Project (P–6951–018).

n. The application is not ready for environmental analysis at this time.

o. *Project Description*: The existing Tallassee Shoals Project consists of: (1) A 365-foot-long, 25-foot-high concrete dam; (2) a 100-kilowatt fixed Kaplan unit within the dam; (3) a 1,400-foot-long headrace canal from the dam to the powerhouse; (4) an 80-foot-long, 11-foot-diameter penstock; (5) a powerhouse containing a single 2.2-megawatt (MW) adjustable Kaplan unit; (6) a 75-foot-long tailrace; and (7) a 100-foot-long, 42-kilovolt transmission line. The project creates a 2,100-foot-long bypassed reach of the Middle Oconee River. The project's total capacity is 2.3 MW and its average annual generation is approximately 6,100 megawatt-hours.

Tallassee Shoals, LLC does not propose any changes to the project's run-of-river operation and required 70 cubic-feet-per-second minimum flow.

p. In addition to publishing the full text of this notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this notice, as well as other documents in the proceeding (e.g., license application) via the internet through the Commission's Home Page (<http://www.ferc.gov>) using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number

field to access the document (P–6951). At this time, the Commission has suspended access to the Commission's Public Reference Room due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19) issued on March 13, 2020. For assistance, contact FERC at FEROnlineSupport@ferc.gov or call toll-free, (866) 208–3676 or (202) 502–8659 (TTY).

You may also register online at <https://ferconline.ferc.gov/FEROnline.aspx> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

q. *Procedural schedule*: The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Issue Deficiency Letter (if necessary)—

January 2022

Request Additional Information—

January 2022

Issue Acceptance Letter—March 2022

Issue Scoping Document 1 for

comments—April 2022

Issue Notice of Ready for Environmental Analysis—July 2022

r. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: September 21, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–20896 Filed 9–24–21; 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: RP21–1127–000.

Applicants: Tuscarora Gas Transmission Company.

Description: Compliance filing: TXP Compliance Filing to be effective 11/1/2021.

Filed Date: 9/20/21.

Accession Number: 20210920–5084.

Comment Date: 5 p.m. ET 10/4/21.

Docket Numbers: RP21–1128–000.

Applicants: Tuscarora Gas Transmission Company.

Description: Compliance filing: 2021 Fuel and Line Loss Report to be effective N/A.

Filed Date: 9/20/21.

Accession Number: 20210920–5095.

Comment Date: 5 p.m. ET 10/4/21.

Docket Numbers: RP21–1129–000.

Applicants: ANR Pipeline Company.

Description: § 4(d) Rate Filing: ANR Best Bid Evaluation Tariff Change to be effective 10/20/2021.

Filed Date: 9/20/21.

Accession Number: 20210920–5120.

Comment Date: 5 p.m. ET 10/4/21.

Docket Numbers: RP21–1130–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 9.21.21 Negotiated Rates—Citadel Energy Marketing LLC R–7705–05 to be effective 11/1/2021.

Filed Date: 9/21/21.

Accession Number: 20210921–5005.

Comment Date: 5 p.m. ET 10/4/21.

Docket Numbers: RP21–1131–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 9.21.21 Negotiated Rates—Citadel Energy Marketing LLC R–7705–06 to be effective 11/1/2021.

Filed Date: 9/21/21.

Accession Number: 20210921–5006.

Comment Date: 5 p.m. ET 10/4/21.

Docket Numbers: RP21–1132–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 9.21.21 Negotiated Rates—Twin Eagle Resource Management, LLC R–7300–22 to be effective 11/1/2021.

Filed Date: 9/21/21.

Accession Number: 20210921–5009.

Comment Date: 5 p.m. ET 10/4/21.

Docket Numbers: RP21–1133–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 9.21.21 Negotiated Rates—Twin Eagle Resource Management, LLC R–7300–23 to be effective 11/1/2021.

Filed Date: 9/21/21.

Accession Number: 20210921–5011.

Comment Date: 5 p.m. ET 10/4/21.

Docket Numbers: RP21–1134–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 9.21.21 Negotiated Rates—Twin Eagle Resource Management, LLC R–7300–24 to be effective 11/1/2021.

Filed Date: 9/21/21.

Accession Number: 20210921–5012.

Comment Date: 5 p.m. ET 10/4/21.

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.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

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: September 21, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–20895 Filed 9–24–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0611; FRL–8950–01–ORD]

Board of Scientific Counselors (BOSC) Sustainable and Healthy Communities Subcommittee Meeting—October 2021

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of a series of virtual meetings of the Board of Scientific Counselors (BOSC) Sustainable and Healthy Communities (SHC) Subcommittee to review the SHC research program. EPA's Sustainable and Healthy Communities (SHC) Research program provides technical solutions, tools, information, and other resources in three topic areas critical to fulfilling the Agency's mission to protect the environment and safeguard public health: Contaminated Sites; Waste and Materials Management; and Healthy and Resilient Communities.

DATES: 1. The meeting will be held over two days via videoconference:

a. Thursday, October 28, 2021, from 12 p.m. to 5 p.m. (EDT); and

b. Friday, October 29, 2021, from 12 p.m. to 5 p.m. (EDT).

Attendees must register by October 27, 2021.

2. A BOSC deliberation videoconference will be held on

November 12, 2021, from 11 a.m. to 2 p.m. (EDT).

Attendees must register by November 10, 2021.

3. A final BOSC deliberation videoconference will be held on November 19, 2021, from 11 a.m. to 2 p.m. (EDT). Attendees must register by November 18, 2021.

Meeting times are subject to change. This series of meetings is open to the public. Comments must be received by October 27, 2021, to be considered by the subcommittee. Requests for the draft agenda or making a presentation at the meeting will be accepted until October 27, 2021.

ADDRESSES: Instructions on how to connect to the videoconference will be provided upon registration at: <https://epa-bosc-shc-subcommittee-mtg.eventbrite.com>.

Submit your comments to Docket ID No. EPA–HQ–ORD–2015–0611 by one of the following methods:

- www.regulations.gov: Follow the online instructions for submitting comments.

- *Note:* comments submitted to the www.regulations.gov website are anonymous unless identifying information is included in the body of the comment.

- *Email:* Send comments by electronic mail (email) to: ORD.Docket@epa.gov, Attention Docket ID No. EPA–HQ–ORD–2015–0611.

- *Note:* comments submitted via email are not anonymous. The sender's email will be included in the body of the comment and placed in the public docket which is made available on the internet.

Instructions: All comments received, including any personal information provided, will be included in the public docket without change and may be made available online at www.regulations.gov. Information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute will not be included in the public docket and should not be submitted through www.regulations.gov or email. For additional information about the EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/dockets/>.

Public Docket: Publicly available docket materials may be accessed *Online* at www.regulations.gov.

Copyrighted materials in the docket are only available via hard copy. The telephone number for the ORD Docket Center is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer (DFO), Tom

Tracy, via phone/voicemail at: 919–541–4334; or via email at: tracy.tom@epa.gov.

Any member of the public interested in receiving a draft agenda, attending the meeting, or making a presentation at the meeting should contact Tom Tracy no later than October 27, 2021.

SUPPLEMENTARY INFORMATION: The Board of Scientific Counselors (BOSC) is a federal advisory committee that provides advice and recommendations to EPA's Office of Research and Development on technical and management issues of its research programs. The meeting agenda and materials will be posted to <https://www.epa.gov/bosc>.

Proposed agenda items for the meeting include, but are not limited to, the following: Waste and sustainable materials management.

Information on Services Available: For information on translation services, access, or services for individuals with disabilities, please contact Tom Tracy at 919–541–4334 or tracy.tom@epa.gov. To request accommodation of a disability, please contact Tom Tracy at least ten days prior to the meeting to give the EPA adequate time to process your request.

Authority: Public Law 92–463, 1, Oct. 6, 1972, 86 Stat. 770.

Mary Ross,

Director, Office of Science Advisor, Policy and Engagement.

[FR Doc. 2021–20935 Filed 9–24–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0741, OMB 3060–0806; FR ID 49953]

Information Collections Being Submitted for Review and Approval to 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, 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. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might “further reduce the information

collection burden for 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 and recommendations for the proposed information collection should be submitted on or before October 27, 2021.

ADDRESSES: Comments should be sent to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Your comment must be submitted into www.reginfo.gov per the above instructions for it to be considered. In addition to submitting in www.reginfo.gov also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to PRA@fcc.gov and to Nicole.Ongele@fcc.gov. Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page <http://www.reginfo.gov/public/do/PRAMain>, (2) look for the section of the web page called “Currently Under Review,” (3) click on the downward-pointing arrow in the “Select Agency” box below the “Currently Under Review” heading, (4) select “Federal Communications Commission” from the list of agencies presented in the “Select Agency” box, (5) click the “Submit” button to the right of the “Select Agency” box, (6) when the list of FCC ICRs currently under review appears, look for the Title 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, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested

concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might “further reduce the information collection burden for small business concerns with fewer than 25 employees.”

OMB Control Number: 3060–0741.

Title: Accelerating Wireline Broadband Deployment by Removing Barriers to Infrastructure Investment, GN Docket No. 17–84.

Form Number(s): N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 4,750 respondents; 471,920 responses.

Estimated Time per Response: 0.5–4.5 hours.

Frequency of Response: On occasion reporting requirements; recordkeeping and third-party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 222 and 251.

Total Annual Burden: 473,440 hours.

Total Annual Cost: No cost.

Needs and Uses: Section 251 of the Communications Act of 1934, as amended, 47 U.S.C. 251, is designed to accelerate private sector development and deployment of telecommunications technologies and services by spurring competition. Section 222(e) is also designed to spur competition by prescribing requirements for the sharing of subscriber list information. These information collection requirements are designed to help implement certain provisions of sections 222(e) and 251, and to eliminate operational barriers to competition in the telecommunications services market. Specifically, these information collection requirements will be used to implement (1) local exchange carriers' (“LECs”) obligations to provide their competitors with dialing parity and non-discriminatory access to certain services and functionalities; (2) incumbent local

exchange carriers' ("ILECs") duty to make network information disclosures; and (3) numbering administration. In November 2017, the Commission adopted new rules concerning certain information collection requirements implemented under section 251(c)(5) of the Act, pertaining to network change disclosures. Most of the changes to those rules applied specifically to a certain subset of network change disclosures, namely notices of planned copper retirements. In addition, the changes removed a rule that prohibits incumbent LECs from engaging in useful advanced coordination with entities affected by network changes. In June 2018, the Commission revised its network change disclosure rules to (1) revise the types of network changes that trigger an incumbent LEC's public notice obligation, and (2) extend the force majeure provisions applicable to copper retirements to all types of network changes. The changes were aimed at removing unnecessary regulatory barriers to the deployment of high-speed broadband networks.

OMB Control Number: 3060-0806.

Title: Universal Service-Schools and Libraries Universal Service Program, FCC Forms 470 and 471.

Form Number: FCC Forms 470 and 471.

Type of Review: Extension of a currently approved collection.

Respondents: State, local or tribal government institutions, and other not-for-profit institutions.

Number of Respondents and

Responses: 43,000 respondents; 67,100 responses.

Estimated Time per Response: 3.5 hours for FCC Form 470 (3 hours for response; 0.5 hours for recordkeeping; 4.5 hours for FCC Form 471 (4 hours for response; 0.5 hours for recordkeeping)).

Frequency of Response: On occasion and annual reporting requirements, and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection

is contained in sections 1, 4(i), 4(j), 201–205, 214, 254, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151–154, 201–205, 218–220, 254, 303(r), 403 and 405.

Total Annual Burden: 273,950 hours.

Total Annual Cost: No Cost.

Needs and Uses: The Commission seeks approval to extend the existing collection 3060–0806 (FCC Forms 470 and 471). Collection of the information on FCC Forms 470 and 471 is necessary so that the Commission and USAC have sufficient information to determine if entities are eligible for funding pursuant to the schools and libraries support mechanism, to determine if entities are complying with the Commission's rules, and to prevent waste, fraud, and abuse. In addition, the information is necessary for the Commission to evaluate the extent to which the E-rate program is meeting the statutory objectives specified in section 254(h) of the 1996 Act, and the Commission's performance goals established in the *E-rate Modernization Order* and *Second E-rate Modernization Order*.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–20927 Filed 9–24–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

[OMB No. 3064–0028]

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to

comment on the renewal of the existing information collection described below (OMB Control No. 3064–0028).

DATES: Comments must be submitted on or before November 26, 2021.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- <https://www.FDIC.gov/regulations/laws/federal>.
- **Email:** comments@fdic.gov. Include the name and number of the collection in the subject line of the message.
- **Mail:** Manny Cabeza (202–898–3767), Regulatory Counsel, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- **Hand Delivery:** Comments may be hand-delivered to the guard station at the rear of the 17th Street building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

Manny Cabeza, Regulatory Counsel, 202–898–3767, mcabeza@fdic.gov, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently approved collection of information:

1. **Title:** Recordkeeping and Confirmation Requirements for Securities Transactions.

OMB Number: 3064–0028.

Form Number: None.

Affected Public: FDIC-Insured Institutions and Certain Employees of the FDIC-Insured Institutions.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN

Information collection description	Type of burden	Obligation to respond	Estimated number of respondents	Estimated frequency of responses	Estimated time per response (hours)	Estimated annual burden (hours)
Maintain Securities Trading Policies and Procedures Officer/Employee Filing of Reports of Personal Securities Trading Transactions—344.9 (assumes 5 officers/employees at each institution with income from securities broker activity).	Recordkeeping Third-Party Disclosure.	Mandatory Mandatory	691 2,073	1 4	1 1	691 8,292

Total Estimated Annual Burden: 8,983 hours.

General Description of Collection: The collection of information requirements are contained in 12 CFR part 344. The

purpose of the regulation is to ensure that purchasers of securities in transactions affected by insured state

nonmember banks are provided with adequate records concerning the transactions. The regulation is also designed to ensure that insured state nonmember banks maintain adequate records and controls with respect to the securities transactions they effect. Finally, this regulation requires officers and employees of FDIC-supervised institutions to report to the FDIC supervised institution certain personal securities trading activity.

Sections 344.4, 344.5, and 344.6 refer to reporting and third party disclosure burdens associated with confirmation of securities transactions. The FDIC assumes that banks automate notifications to customers of securities transactions, and would automate these notifications even if 12 CFR 344 were not in place. The automation includes the recordkeeping and disclosure of the confirmation of securities transactions. As such, FDIC believes that the activities associated with sections 344.4, 344.5, and 344.6 are all done in the ordinary course business, and do not represent PRA burden.

Potential respondents to this IC are all FDIC-supervised institutions that effect securities transactions for customers. Respondents include institutions that conduct securities transactions themselves or that conduct securities transactions through a broker/dealer. To estimate the annual number of respondents, FDIC referenced the number of FDIC-supervised institutions that reported exercising fiduciary powers as of the first quarter of 2021,¹ which is reported on item 2 of Call Report Schedule RC-T.

As of March 31, 2021, 691 FDIC-supervised institutions reported exercising fiduciary powers.² These 691 entities are subject to the PRA requirements in 12 CFR 344.8. Thus, FDIC estimates 691 respondents to the line items corresponding to this section. In the previous renewal of this information collection, the FDIC estimated 680 respondents to this IC; this estimate was derived by counting the number of FDIC-supervised institutions with income from securities brokerage activity. The increase in the estimated number of respondents from 680 to 691 is a result of a change in estimation methodology due to a change in the call report reporting requirements.³

The line item corresponding to 12 CFR 344.9 applies to officers and employees of FDIC-supervised institutions who “make investment recommendations or decisions for the

accounts of customers; participate in the determination of such recommendations or decisions; or in connection with their duties, obtain information concerning which securities are being purchased or sold or recommend such action.”⁵ Excluded from this requirement are “transactions for the benefit of the officer or employee over which the officer or employee has no direct or indirect influence or control; transactions in registered investment company shares; transactions in government securities; and all transactions involving in the aggregate \$10,000 or less during the calendar quarter.”⁶ The FDIC does not currently have access to data on how many officers or employees are required to report trading activities in which they have a beneficial interest in accordance with Section 344.9. In the estimate for the previous ICR, it was assumed that five officers or employees per FDIC-supervised institution affected by this IC who would respond to this line item. Based on supervisory experience, FDIC believes that most of the smaller FDIC-supervised institutions do not have any personnel subject to Section 344.9.⁷ Accordingly, FDIC has reduced the assumed number of officers or employees per FDIC-supervised institution who would respond to this line item from five to three. FDIC therefore estimates 2,073 respondents per year to this line item.⁸ This estimate constitutes a decrease of 1,327 in the estimated annual number of respondents to this IC.

Section 344.8 requires FDIC-supervised institutions to establish processes and procedures for assigning responsibility for supervising employees and officers who are involved with processing, documenting, and executing securities transactions for customers, and for ensuring equitable treatment of parties to a security transaction, and of customers who submit orders for the same security or securities at approximately the same time. Policies and procedures are generally reviewed and updated annually. FDIC therefore estimate one response per respondent to this line item as FDIC believes that institutions are more likely to update their policies and procedures annually rather than monthly. This estimate represents a decrease of 11 responses per respondent.

FDIC has also revised its estimate of the time required to respond to the requirements of Section 344.8 to one hour per response. This estimate represents an increase of 0.75 hours per

response from the estimate included in the 2018 renewal and is based on the FDIC's experience with this information collection.

FDIC estimates one hour per response for the burden related to Section 344.9. This estimate represents a decrease of 0.5 hours per response from the estimate included in the 2018 renewal and is also based on the FDIC's experience with this information collection.

The total estimated annual burden for this information collection is 8,983 hours, which is a decrease of 56,297 hours from the estimate included in the previous renewal.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, on September 19, 2021.

Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

FR Doc. 2021-20808 Filed 9-24-21; 8:45 am

BILLING CODE 6714-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained

¹ RIS variable TREXER.

² FDIC Call Report data, March 2021.

⁵ 12 CFR 344.9(a).

⁶ 12 CFR 344.9(b)

on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551-0001, not later than October 12, 2021.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Stilwell Activist Investments, L.P., Stilwell Activist Fund, L.P., and Stilwell Value Partners VII, L.P., together known as The Stilwell Group, Stilwell Value LLC, as general partner of each of the limited partnerships, all of New York, New York; and Joseph D. Stilwell, San Juan, Puerto Rico, as managing member of Stilwell Value LLC; a group acting in concert, to acquire voting shares of CIB Marine Bancshares, Inc., Brookfield, Wisconsin, and thereby indirectly acquire voting shares of CIBM Bank, Champaign, Illinois.*

Board of Governors of the Federal Reserve System, September 22, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-20880 Filed 9-24-21; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[Notice-PCSCOTUS-2021-01; Docket No. PCSCOTUS-2021-0001; Sequence No. 4]

Office of Asset and Transportation Management; Presidential Commission on the Supreme Court of the United States; Notification of Upcoming Public Virtual Meeting and Request for Public Comment

AGENCY: Office of Government-wide Policy, General Services Administration (GSA).

ACTION: Request for public comment; meeting notice.

SUMMARY: GSA is accepting written public comments on the work of the Presidential Commission on the Supreme Court of the United States (Commission). Further, GSA is providing notice of an open public virtual meeting of the Commission in

accordance with the requirements of the Federal Advisory Committee Act. The purpose of this meeting is for the Commissioners to deliberate on the report that the Commission is charged with preparing pursuant to *Executive Order 14023*. For more information on the meeting agenda, please see the **SUPPLEMENTARY INFORMATION** section of this notice. This meeting is open to the public and will be live-streamed at www.whitehouse.gov/pcscotus/. Materials relevant to the public meeting will be posted at www.whitehouse.gov/pcscotus/ prior to the meeting.

DATES: The Commission will hold a public virtual meeting on October 15, 2021 from 10:00 a.m. to 5:00 p.m., Eastern Standard Time (EST).

ADDRESSES: This meeting will be conducted virtually on the internet. Interested individuals must register to attend as instructed below.

Procedures for Attendance and Public Comment

Attendance. This meeting is open to the public and the Commission encourages the public's attendance. To attend this public virtual meeting, please send an email with the Subject: Registration. In the body of the email, provide your full name, organization (if applicable), email address, and phone number to the Designated Federal Officer, at info@pcscotus.gov. Registration requests must be received by 5:00 p.m. ET, on October 13, 2021. Registrations received after this day/time may not be processed.

Public Comments. Written public comments are being accepted via <http://www.regulations.gov>, the Federal eRulemaking portal throughout the life of the Commission. To submit a written public comment, go to <http://www.regulations.gov> and search for PCSCOTUS-2021-0001. Then, click on the "Comment" button that shows up in the search results. Select the link "Comment" that corresponds with this notice. Follow the instructions provided on the screen. Please include your name, company name (if applicable), and "PCSCOTUS-2021-0001, Notification of Upcoming Public Virtual Meeting and Request for Public Comment" on your attached document (if applicable). Public comments meeting our public comment policy, included under **SUPPLEMENTARY INFORMATION**, will be shared on [Regulations.gov](http://www.regulations.gov). Comments provided by 5:00 p.m. ET, on October 11, 2021 will be provided to the Commission members in advance of the October 15 public meeting. Comments submitted after this date will still be provided to

the Commission members, but please be advised that Commission members may not have adequate time to consider the comments prior to the meeting.

Special accommodations. For information on services for individuals with disabilities, or to request accommodation of a disability, please contact the Designated Federal Officer at least 10 business days prior to the meeting to give GSA as much time as possible to process the request.

FOR FURTHER INFORMATION CONTACT: For information on the public virtual meeting, contact Dana Fowler, Designated Federal Officer, Office of Government-wide Policy, General Services Administration, at info@pcscotus.gov, 202-501-1777.

SUPPLEMENTARY INFORMATION:

Background

The Administrator of GSA established the Commission under the Federal Advisory Committee Act on April 26, 2021 pursuant to *Executive Order 14023, Establishment of the Presidential Commission on the Supreme Court of the United States*, issued on April 9, 2021. Per the Executive Order, the Commission shall produce a report for the President that includes the following:

(i) An account of the contemporary commentary and debate about the role and operation of the Supreme Court in our constitutional system and about the functioning of the constitutional process by which the President nominates and, by and with the advice and consent of the Senate, appoints Justices to the Supreme Court;

(ii) The historical background of other periods in the Nation's history when the Supreme Court's role and the nominations and advice-and-consent process were subject to critical assessment and prompted proposals for reform; and

(iii) An analysis of the principal arguments in the contemporary public debate for and against Supreme Court reform, including an appraisal of the merits and legality of particular reform proposals.

Meeting Agenda

The purpose of this meeting is for the Commissioners to deliberate on the report that the Commission is charged with preparing pursuant to *Executive Order 14023*. The agenda and deliberations will be organized in accordance with the tentative structure of the report.

- Chapter 1: Setting the Stage: The Genesis of the Reform Debate and the Commission's Mission

- Chapter 2: Membership and Size of the Court
- Chapter 3: Length of Service and Turnover of Justices on the Court
- Chapter 4: The Court's Role in the Constitutional System
- Chapter 5: Case Selection and Review: Docket, Rules, and Practices

Public Comment Policy

The Commission asks that written public comments be respectful and relevant to the work of the Commission. All comments are reviewed before they are shared with the Commission or posted online. Comments that include the following will not be shared on *Regulations.gov*:

- Vulgar, obscene, profane, threatening, or abusive language; personal attacks of any kind.
- Discriminatory language (including hate speech) based on race, national origin, age, gender, sexual orientation, religion, or disability.
- Endorsements of commercial products, services, organizations, or other entities.
- Repetitive posts (for example, if you submit the same material multiple times).
- Spam or undecipherable language (gratuitous links will be viewed as spam).
- Copyrighted material.
- Links to external sites.
- Images or videos.
- Solicitation of funds.
- Procurement-sensitive information.
- Surveys, polls, and questionnaires subject to the Office of Management and Budget Paperwork Reduction Act clearance.
- Personally Identifiable Information (PII) or Sensitive Information (SI).
- Off-topic posts.
- Media inquiries.

Thank you for your interest in the Presidential Commission on the Supreme Court of the United States. We look forward to hearing from you.

Krystal J. Brumfield,
Associate Administrator, Office of
Government-wide Policy.

[FR Doc. 2021-20822 Filed 9-24-21; 8:45 am]

BILLING CODE 6820-14-P

OFFICE OF GOVERNMENT ETHICS

Updated OGE Senior Executive Service Performance Review Board

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice.

SUMMARY: Notice is hereby given of the appointment of a member to the OGE

Senior Executive Service (SES)
Performance Review Board.

DATES: September 27, 2021.

FOR FURTHER INFORMATION CONTACT:

Shelley K. Finlayson, Chief of Staff and Program Counsel, Office of Government Ethics, Suite 500, 1201 New York Avenue NW, Washington, DC 20005-3917; Telephone: 202-482-9300; TTY: 800-877-8339; FAX: 202-482-9237.

SUPPLEMENTARY INFORMATION: 5 U.S.C. 4314(c) requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management at 5 CFR part 430, subpart C and 430.310 thereof in particular, one or more Senior Executive Service performance review boards. As a small executive branch agency, OGE has just one board. In order to ensure an adequate level of staffing and to avoid a constant series of recusals, the designated members of OGE's SES Performance Review Board are being drawn, as in the past, in large measure from the ranks of other executive branch agencies. The board shall review and evaluate the initial appraisal of each OGE senior executive's performance by his or her supervisor, along with any recommendations in each instance to the appointing authority relative to the performance of the senior executive. This notice updates the membership of OGE's SES Performance Review Board as it was most recently published at 84 FR 44898 (August 27, 2019).

Approved: September 22, 2021.

Emory A. Rounds, III,
Director, U.S. Office of Government Ethics.

Due to the retirement from government service of David Maggi, the following official has been appointed to the SES Performance Review Board of the Office of Government Ethics: Sean Dent, Senior Deputy General Counsel and Designated Agency Ethics Official, Federal Housing Finance Agency. The remaining Board members are Shelley K. Finlayson (Chair), Chief of Staff and Program Counsel, Office of Government Ethics; Kathleen Silbaugh, General Counsel, Office of the General Counsel, National Transportation and Safety Board; and Peter J. Constantine, Associate Solicitor for Legal Counsel, Office of the Solicitor, Department of Labor.

[FR Doc. 2021-20888 Filed 9-24-21; 8:45 am]

BILLING CODE 6345-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-21DZ]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Harm Reduction Toolkit for Non-Prescription Syringe Sales in Community Pharmacies to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on April 5, 2021, to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting

“Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Harm Reduction Toolkit for Non-Prescription Syringe Sales in Community Pharmacies—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Injection drug use, through shared use of injection equipment, increases risk of acquiring blood borne pathogens such as HIV and hepatitis C virus. While stopping injection drug use is an optimal goal for preventing transmission of bloodborne pathogens among persons who inject drugs (PWID), it is not always achievable. However, use of sterile needles and syringes, for each injection, can significantly reduce risk of acquiring bloodborne pathogens and access to sterile syringes can reduce needle sharing among PWID.

Community pharmacies are in a unique position to provide access to sterile syringes through non-prescription syringe sales (NPSS). Pharmacies are in this position partly because they are among the most accessible of healthcare settings. In fact, approximately 90% of urban costumers live within two miles of a pharmacy, and 70% of rural costumers are within 15 miles of a pharmacy. Pharmacies also

have extended hours of operations making them more accessible to patients. While pharmacies represent potential sites for NPSS, education and tools are needed to build pharmacists' NPSS-related skills and to support pharmacists in the delivery of NPSS and other harm reduction services.

The overarching aim of this project is to create harm reduction products that can help: (1) Facilitate greater access to sterile syringes through pharmacy-based NPSS, (2) minimize the burden of NPSS distribution on pharmacists, and (3) improve pharmacy personnel's understanding of, and skills with, NPSS efforts. The project will demonstrate how pharmacy personnel can use a contractor developed harm reduction kit for PWID and online training videos for pharmacy personnel on NPSS, for HIV prevention.

CDC requests OMB approval to collect standardized data from an in-field demonstration and evaluation of three contractor developed resources for harm reduction: Harm reduction kit for PWID; online training videos for pharmacists and pharmacy personnel regarding NPSS; and a resource website for PWID. The in-field demonstration and evaluation will take place at 12 project pharmacies over one six-week period. The information collection has three primary components: (1) Online pre-test and post-test surveys, (2) number of pharmacy syringe sales and service referrals, and (3) website usage (for the training website and the resource website for PWID). Each pharmacy personnel who participates in the in-field demonstration will attend an orientation meeting, complete a one-time online pre-test survey, complete online training regarding NPSS, and a one-time online post-test survey. The pre-test survey will be completed in the

week prior to the participants being given access to online training videos for pharmacists and pharmacy personnel regarding NPSS. The post-test survey will be completed in the week following the one-week training period. An estimated 60 pharmacy personnel will complete the pre-test and post-test surveys. Data from the pre/post-test surveys will be collected entirely online. The purpose of the surveys is to assess pharmacy personnel's skills and knowledge pertaining to NPSS before and after access to the NPSS online training.

Data on pharmacy syringe sales and service referrals (e.g., referrals for HIV testing and substance use treatment) will be collected from each of the 12 participant pharmacy's store or log records before and after the one-week training period. Each participant pharmacy's manager will conduct a one-time data collection of aggregated syringe sales and service referrals data from the 30-day period before and after the training period. The purpose of the data is to describe syringe sales and service referrals before and after pharmacy personnel's access to the NPSS online training. Lastly, one project director will determine website usage of the training website and resource locator for PWID.

Training website usage data will be paired with the pre-test and post-test surveys and skill scores and analyzed for correlations between usage and knowledge, comfort, and use of NPSS skills. The numbers of syringe customers and service referrals and usage of the resource website for PWID will be described.

CDC requests approval for an estimated 217 total annual burden hours. There are no other costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Pharmacists and pharmacy technicians	Pharmacy staff orientation protocol	60	1	45/60
Pharmacists and pharmacy technicians	Pre-test survey	60	1	30/60
Pharmacists and pharmacy technicians	Post-test survey *	60	1	130/60
Pharmacy manager	Pharmacy syringe sales and service referrals	12	1	1
Project director	Website usage	1	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.

[FR Doc. 2021–20842 Filed 9–24–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Center for Preparedness and Response, (BSC, CPR)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, Center for Preparedness and Response, (BSC, CPR). This is a virtual meeting that is open to the public, limited only by the number of internet conference accesses available, which is 500. Pre-registration is required by accessing the link in the **ADDRESSES** section.

DATES: The meeting will be held on November 2, 2021, from 12:30 p.m. to 4:30 p.m., EDT.

ADDRESSES: Zoom Virtual Meeting. If you wish to attend the virtual meeting, please pre-register by accessing the link at: https://cdc.zoomgov.com/webinar/register/WN_ozgFewBJSXCWfEXwqrA2cw. Instructions to access the Zoom virtual meeting will be provided in the link following registration.

FOR FURTHER INFORMATION CONTACT: Dometa Ouisley, Office of Science and Public Health Practice, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop—H21-6, Atlanta, Georgia 30329-4027, Telephone: (404) 639-7450; Facsimile: (678) 669-1667; Email: DOuisley@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The Board is charged with providing advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health (ASH), the Director, Centers for Disease Control and Prevention (CDC), and the Director, Center for Preparedness and Response (CPR), concerning strategies and goals for the programs and research within CPR, monitoring the overall strategic direction and focus of the CPR Divisions and Offices, and administration and oversight of peer review for CPR scientific programs. For additional information about the Board, please visit: <https://www.cdc.gov/cpr/bsc/index.htm>.

Matters To Be Considered: The agenda will include: (1) CPR Director Update;

(2) CPR Division Updates and Discussion; (3) COVID-19 Response Update; (4) The Data Strategy and Execution Workgroup: An Interagency Approach to Coordinating Data and Analytics Efforts to Support the Whole-of Government COVID-19 Response; and (5) CPR Polio Containment Workgroup (PCWG) Update. Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021-20928 Filed 9-24-21; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-0338; Docket No. CDC-2021-0101]

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 Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S. This Extension permits CDC to collect a list of ingredients added to tobacco in the manufacture of smokeless tobacco products, and a specification of the quantity of nicotine contained in each

product. CDC's Office of Smoking and Health (OSH) has been delegated with the responsibility for implementing the required information collection by HHS.

DATES: CDC must receive written comments on or before November 26, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0101 by any of the following methods:

- **Federal eRulemaking Portal:** [Regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- **Mail:** Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, 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](https://www.regulations.gov).

Please note: Submit all comments through the Federal eRulemaking portal ([regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, 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;
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; and
5. Assess information collection costs.

Proposed Project

Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U. S. (OMB Control No. 0920–0338, Exp. 4/30/2022)—Extension—National Center for Chronic Disease and Public Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Smokeless tobacco products (SLT) are associated with many health problems. Using smokeless tobacco: Can lead to nicotine addiction; causes cancer of the mouth, esophagus, and pancreas; is associated with diseases of the mouth; can increase risks for early delivery and

stillbirth when used during pregnancy; can cause nicotine poisoning in children; and may increase the risk for death from heart disease and stroke.

The CDC’s Office on Smoking and Health (OSH) is the lead federal agency for comprehensive tobacco prevention and control. As required by the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA, 15 U.S.C. 4401 *et seq.*, Pub. L. 99–252), CDC collects a list of ingredients added to tobacco in the manufacture of smokeless tobacco products and a specification of the quantity of nicotine contained in each product. HHS has delegated responsibility for implementing the required information collection to CDC’s OSH. Respondents are manufacturers, packagers, or importers (or their representatives) of smokeless tobacco products. Respondents are not required to submit specific forms; however, they are required to meet reporting guidelines and to submit the ingredient report by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies that are required to report ingredients added to other consumer products, and to report on the quantity of nicotine contained in each smokeless tobacco product as specified in previous **Federal Register** Notices. Respondents may submit the

required information to CDC through a designated representative. The information collection is subject to strict confidentiality provisions.

Ingredient and nicotine analysis reports for new SLT products are due at the time of first importation. Thereafter, ingredient reports are due annually on March 31. Information is submitted to CDC by mailing a written report on the respondent’s letterhead. Electronic mail submissions are not accepted. Annual submission reports are mailed to Attention: FCLAA Program Manager, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS S107–7, Atlanta, GA 30341–3717.

Following receipt of the annual nicotine and ingredient report, CDC issues a Certificate of Compliance to the respondent. As deemed appropriate by the Secretary of HHS, HHS is authorized to use the information to report to Congress the health effects of ingredients, research activities related to the health effects of ingredients, and other information that the Secretary determines to be of public interest.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 18,843. OMB approval is requested for three years.

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)
Smokeless Tobacco Manufacturers, Packagers, and Importers.	SLT Ingredient Report	11	1	6.5	71.5
Smokeless Tobacco Manufacturers, Packagers, and Importers.	SLT Nicotine Data Reporting ..	11	1	1,706.5	18,771.5
Total					18,843

Jeffrey M. Zirger,
*Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.*
[FR Doc. 2021–20845 Filed 9–24–21; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0106; NIOSH–344]

Interventions To Prevent Work-Related Stress and Support Health Worker Mental Health; Request for Information

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Request for information.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease

Control and Prevention (CDC), announces an opportunity for the public to provide information and comments on current evidence-based, workplace and occupational safety and health interventions to prevent work-associated stress, support stress reduction, and foster positive mental health and well-being among the nation’s health workers. Information and comments are also requested on interventions under development and research in progress to support and promote the mental health and well-being of health workers. NIOSH is seeking information on related best practices, promising practices, or

successful programs related to providing stress prevention and mental health services to health workers. Examples of such services include, but are not limited to, employee assistance programs, screenings, supervisor trainings, workplace policies, talk therapy, mindfulness, peer support, and mobile apps.

DATES: Comments must be received by November 26, 2021.

ADDRESSES: Comments may be submitted through either of the following two methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov> (follow the instructions for submitting comments), or

- *By Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS C-34, 1090 Tusculum Avenue, Cincinnati, Ohio 45226-1998.

Instructions: All written submissions received in response to this notice must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC-2021-0106; NIOSH-344) for this action. All relevant comments, including any personal information provided, will be posted without change to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Rachel Weiss, Program Analyst; 1090 Tusculum Ave., MS: C-48, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email NIOSHregs@cdc.gov.

SUPPLEMENTARY INFORMATION: The Centers for Disease Control and Prevention (CDC) is charged by the American Rescue Plan Act of 2021 (Pub. L. 117-2, sec. 2704) with educating health workers and first responders on primary prevention of mental health conditions and substance use disorders and encouraging these professionals to identify and seek support for their own mental health or substance use concerns. Accordingly, CDC's National Institute for Occupational Safety and Health (NIOSH) announces an opportunity for the public to provide information and comments on evidence-based workplace and occupational safety and health interventions, policies, or other activities relevant to health care professionals and first responders, including those at the population, organizational, or individual levels. Information and comments are requested on related interventions under development and research in progress. NIOSH is also seeking information on related best practices, promising practices, or successful programs related to providing stress

prevention and mental health services to health workers.

Health workers include everyone who works in healthcare—for public and private providers, in clinical and community settings—such as first responders, admitting and ward clerks, laboratory technologists and technicians, nurses, physicians, environmental services workers, and food service staff in healthcare settings. Health workers face many demands at work, which may include difficult working conditions, long work hours, rotating and irregular shifts, exposure to human suffering and death, and increased risks for personal exposure to disease and harm.¹ The COVID-19 pandemic has exacerbated these challenges and contributed to new and worsening mental health concerns, including burnout, compassion fatigue, depression, anxiety, substance use disorders, and suicidal ideation. These concerns, in turn, can affect workers' overall health, job performance, and patient care and safety.²

Many lower-paid or part-time health workers—such as home health aides, orderlies, medical assistants, phlebotomists, and pharmacy aides—may have experienced barriers preventing access to health care services and information, including financial challenges, lack of health insurance coverage, or lack of adequate transportation. They can also face lack of recognition and civility (including threatened and actual workplace violence) for the important work they do. Even health workers who are not on the frontlines or at high risk of infection may still encounter work demands that cause poor mental health outcomes.³

Public health workers are also at increased risk for negative mental health consequences when responding to public health emergencies, such as the COVID-19 pandemic, where they must operate under high-stakes conditions for extended periods of time without relief.⁴

¹ National Occupational Research Agenda (NORA) Healthcare and Social Assistance Council. *National Occupational Research Agenda for Healthcare and Social Assistance (HCSA)*. February 2019. https://www.cdc.gov/nora/councils/hcsa/pdfs/National_Occupational_Agenda_for_HCSA_February_2019-508.pdf.

² National Academy of Medicine. *Strategies to Support the Health and Well-Being of Clinicians during the COVID-19 Outbreak*. <https://nam.edu/initiatives/clinician-resilience-and-well-being/clinician-well-being-strategies-during-covid-19/>.

³ See *supra* note 1.

⁴ Bryant-Genevier J, Rao CY, Lopes-Cardozo B, et al. *Symptoms of Depression, Anxiety, Post-Traumatic Stress Disorder, and Suicidal Ideation Among State, Tribal, Local, and Territorial Public Health Workers During the COVID-19 Pandemic* —

NIOSH is interested in receiving comments and other relevant, evidence-based information from a variety of partners, including employers, labor unions, workers, researchers, treatment providers, and government agencies at all levels (Federal, State, Territorial, local, and Tribal). Information provided, including narrative evidence, data, or anecdotes, will support nation-wide efforts to raise awareness of mental health concerns, identify best practices to prevent and reduce work stress and related adverse mental health outcomes, identify workplace and community supports, and reduce stigma related to seeking and receiving care. NIOSH may use the information provided to assimilate the best available evidence; develop a repository of best practices, resources, and interventions; identify and adapt tools; improve data and surveillance; and develop trainings and resources to inform and support employer policy change. NIOSH will also generate awareness by conducting a national social marketing campaign to provide tools and resources to employers, normalize the conversation around mental health, and lower barriers for health workers seeking care for mental health.

Commenters are not required to respond to the questions below and may respond to as many or few as desired. While all inputs are welcomed, comments addressing the following questions are especially helpful:

Questions for Workplaces With Interventions and Services in Place

1. Please tell us about your experience with the development of any preventive interventions currently in place in your workplace to help health workers avoid work-related stress and maintain or improve their mental health and well-being. Describe the intervention's origins and basis, its target population, evaluation or outcome measures, challenges and successes, as well as any other information you think is noteworthy.

2. Please tell us about your experience with the development of any diagnostic and/or therapeutic services offered in your workplace by the employer or union to health workers who are experiencing stress or difficulties with their mental health and well-being. Describe the services' origins and bases, their target population, evaluation or outcome measures, challenges and successes, as well as any other information you think is noteworthy.

3. For both preventive interventions and diagnostic/treatment services in your workplace, please describe how widely the services are used, how stigma associated with seeking mental health care is addressed, and how health workers are encouraged to participate. In your experience, how does the workplace benefit from implementing interventions or offering services to health workers to prevent/reduce work-related stress, to decrease stigma related to seeking and receiving care, and to improve the mental health and well-being of health workers?

4. Please describe any programs you are aware of that help employers to fund or otherwise develop interventions or services to support health worker mental health and well-being.

Questions About Workplaces

5. Please tell us about your experience with any workplace policies designed to protect workers from stress and adverse mental health outcomes and to address these issues. Describe the part(s) of your organization involved in work-associated stress prevention efforts.

Questions About Health Workers' Communication Preferences

6. Please tell us about your workplace's most effective methods of informing health workers about available interventions, services, and workplace practices and policies, including but not limited to: Notification channels, trusted messengers (e.g., upper management, front line supervisor, union representatives), and efforts to reach workers who are underserved by mental health/behavioral health resources.

7. In your experience, do workers seek mental health and well-being information outside the workplace and, if so, where (e.g., community-based, faith-based)? Do health workers generally find sources of information outside the workplace more trustworthy and credible than employer-based programs? If so, what is the basis for this understanding and what efforts have you undertaken to address such concerns?

In addition to the specific questions above, NIOSH would also like to hear from researchers currently conducting research on stress, burnout, and other

mental health and well-being concerns among a broad range of health workers.

John J. Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

[FR Doc. 2021-20931 Filed 9-24-21; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-0210; Docket No. CDC-2021-0102]

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 continuing information collection project titled List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products. The proposed collection allows CDC's Office of Smoking and Health (OSH) to collect information about the ingredients used in cigarette products, a responsibility that has been delegated to CDC by HHS.

DATES: CDC must receive written comments on or before November 26, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0102 by any of the following methods:

- **Federal eRulemaking Portal:** *Regulations.gov.* Follow the instructions for submitting comments.
- **Mail:** Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-H21-8, 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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, 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;

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; and

5. Assess information collection costs.

Proposed Project

List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products (OMB Control No. 0920-0210, Exp. 4/30/2022)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP),

Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Cigarette smoking is the leading preventable cause of premature death and disability in our nation. Each year more than 480,000 deaths occur as the result of cigarette smoking-related diseases. The CDC's Office on Smoking and Health (OSH) is the lead federal agency for comprehensive tobacco prevention and control. Since 1986, as required by the Comprehensive Smoking Education Act (CSEA) of 1984, which amended the Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. 1335a, CDC has collected information about the ingredients used in cigarette products. HHS has delegated responsibility for implementing the required information collection to CDC's OSH. Respondents are commercial cigarette manufacturers, packagers, or importers (or their representatives), who

are required by FCLAA to submit ingredient reports to HHS on an annual basis.

Respondents are not required to submit specific forms; however, they are required to submit a list of all ingredients used in their products. CDC requires the ingredient report to be submitted by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products. The information collected is subject to strict confidentiality provisions.

Ingredient reports are due annually on March 31. Information is submitted to CDC by mailing or faxing a written report on the respondent's letterhead. All faxed lists should be followed up with a mailed original. Electronic mail submissions are not accepted. Mail Annual Ingredient Submissions to

Attention: FCLAA Program Manager, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS S107-7, Atlanta, GA 30341-3717.

Upon receipt and verification of the annual ingredient report, CDC issues a Certificate of Compliance to the respondent. As deemed appropriate by the Secretary of HHS, HHS is authorized to use the information to report to Congress the health effects of ingredients, research activities related to the health effects of ingredients, and other information that the Secretary determines to be of public interest.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 358. OMB approval is requested for three years.

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)
Business Entities	N/A	55	1	6.5	358
Total					358

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.

[FR Doc. 2021-20844 Filed 9-24-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-0666; Docket No. CDC-2021-0100]

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 National Healthcare Safety Network (NHSN). NHSN is the nation's most widely used healthcare-associated infection tracking system, providing facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections.

DATES: CDC must receive written comments on or before November 26, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0100 by any of the following methods:

- *Federal eRulemaking Portal:* [Regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21-8, 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](https://www.regulations.gov).

Please note: Submit all comments through the Federal eRulemaking portal ([regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21-8, 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;
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; and
5. Assess information collection costs.

Proposed Project

National Healthcare Safety Network (NHSN) (OMB Control No. 0920–0666, Exp. 12/31/2023)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities in the National Healthcare Safety Network (NHSN) (OMB Control Number 0920–0666). NHSN provides facilities, states, regions, and the nation with data necessary to identify problem areas, measure the progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs) nationwide. NHSN allows healthcare facilities to track blood safety errors and various healthcare-associated infection prevention practice methods such as healthcare personnel influenza vaccine status and corresponding infection control adherence rates.

NHSN currently has six components: Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), and the Dialysis Component. NHSN's planned

Neonatal Component is expected to launch during the winter of 2021, and will focus on premature neonates and the healthcare-associated events that occur as a result of their prematurity. This component will be released with one module, which includes Late Onset Sepsis (LOS) and Meningitis. LOS and Meningitis are common complications of extreme prematurity. These infections result in a prolongation of hospital stay, increased cost, and risk of morbidity and mortality. The data for this module will be electronically submitted, allowing more hospital personnel to be available to care for patients and reducing annual burden across healthcare facilities. Additionally, LOS data will be utilized for prevention initiatives.

Data reported under the Patient Safety Component are used to determine the magnitude of the healthcare-associated adverse events and trends in the rates of events, in the distribution of pathogens, and in the adherence to prevention practices. Data will help detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data is being used to describe the epidemiology of antimicrobial use and resistance, and to better understand the relationship of antimicrobial therapy to this rising problem.

Under the Healthcare Personnel Safety Component (HPS), protocols and data on events—both positive and adverse—are used to determine: (1) the magnitude of adverse events in healthcare personnel, and (2) compliance with immunization and sharps injuries safety guidelines.

The Biovigilance (BV) Component collects data on adverse reactions and incidents associated with blood transfusions. Data is reported and analyzed to provide national estimates of adverse reactions and incidents.

Under the Long-Term Care Facility (LTCF) Component, data is captured from skilled nursing facilities. Reporting methods under the LTCF component have been created by using forms from the PS Component as a model with modifications to specifically address the specific characteristics of LTCF residents and the unique data needs of these facilities reporting into NHSN. The Respiratory Tract Infection Form (RTI), titled “Denominators for Healthcare Associated Infections (HAIs): Respiratory Tract Infections,” will not to be used by NHSN users, but rather as part of an EIP project with 4 EIP sites. The purpose of this form is to allow testing prior to introducing a new module and forms to NHSN users. The

CDC's Epidemiology Research & Innovations Branch (ERIB) team will use the form to perform field testing of variables to explore the utilization, applicability, and data collection burden associated with these variables. This process will inform areas of improvement prior to incorporating the new module, including protocol, forms, and instructions into NHSN.

The Dialysis Component offers a simplified user interface for dialysis users to streamline their data entry and analyses processes, as well as provide options for expanding in the future to include dialysis surveillance in settings other than outpatient facilities.

The Outpatient Procedure Component (OPC) gathers data on the impact of infections and outcomes related to operative procedures performed in Ambulatory Surgery Centers (ASCs). The OPC is used to monitor two event types: Same Day Outcome Measures and Surgical Site Infections (SSIs).

NHSN has increasingly served as the operating system for HAI reporting compliance through legislation established by the states. As of April 2020, 36 states, the District of Columbia and the City of Philadelphia, Pennsylvania have opted to use NHSN as their primary system for mandated reporting. Reporting compliance is completed by healthcare facilities in their respective jurisdictions, with emphasis on those states and municipalities acquiring varying consequences for failure to use NHSN. Additionally, healthcare facilities in five U.S. territories (Puerto Rico, American Samoa, the U.S. Virgin Islands, Guam, and the Northern Mariana Islands) are voluntarily reporting to NHSN. Additional territories are projected to follow with similar use of NHSN for reporting purposes.

NHSN's data is used to aid in the tracking of HAIs and guide infection prevention activities/practices that protect patients. The Centers for Medicare and Medicaid Services (CMS) and other payers use these data to determine incentives for performance at healthcare facilities across the U.S. and surrounding territories, and members of the public may use some protected data to inform their selection among available providers. Each of these parties is dependent on the completeness and accuracy of the data. CDC and CMS work closely and are fully committed to ensuring complete and accurate reporting, which are critical for protecting patients and guiding national, state, and local prevention priorities. CMS collects some HAI data and healthcare personnel influenza vaccination summary data,

which is done on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs, while others may report data required by a federal mandate. Facilities that fail to report quality measure data are subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. CMS links their quality reporting to payment for Medicare-eligible acute care hospitals, inpatient rehabilitation facilities, long-term acute care facilities, oncology hospitals, inpatient psychiatric facilities, dialysis facilities, and

ambulatory surgery centers. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS's quality reporting programs to receive full payment.

Still, many healthcare facilities, even in states without HAI reporting legislation, submit limited HAI data to NHSN voluntarily. NHSN's data collection updates continue to support the incentive programs managed by CMS. For example, survey questions support requirements for CMS' quality reporting programs. Additionally, CDC

has collaborated with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on recruiting nursing homes to report HAI data to NHSN and to retain their continued participation.

NHSN was previously approved in December 2020 for 1,321,991 burden hours. The proposed changes in this new ICR include revisions to 10 data collection forms and no new forms for a total of 86 proposed data collection forms. In this Revision, CDC requests OMB approval for an estimated 1,718,591 annual burden hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Form number & name	Number of respondents	Number of responses per respondent	Avg. burden per response (hours)	Total burden (hours)
57.100 NHSN Registration Form	2,000	1	5/60	167
57.101 Facility Contact Information	2,000	1	10/60	333
57.103 Patient Safety Component—Annual Hospital Survey	6,765	1	90/60	10,148
57.104 Facility Administrator Change Request Form	800	1	5/60	67
57.105 Group Contact Information	1,000	1	5/60	83
57.106 Patient Safety Monthly Reporting Plan	7,821	12	15/60	23,463
57.108 Primary Bloodstream Infection (BSI)	5,775	5	38/60	18,288
57.111 Pneumonia (PNEU)	1,800	2	30/60	1,800
57.112 Ventilator-Associated Event	5,463	8	28/60	20,395
57.113 Pediatric Ventilator-Associated Event (PedVAE)	334	1	30/60	167
57.114 Urinary Tract Infection (UTI)	6,000	5	20/60	10,000
57.115 Custom Event	600	91	35/60	31,850
57.116 Denominators for Neonatal Intensive Care Unit (NICU)	1,100	12	4/60	880
57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	500	12	5/60	500
57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	5,500	60	5/60	27,500
57.120 Surgical Site Infection (SSI)	6,000	9	35/60	31,500
57.121 Denominator for Procedure	6,000	602	10/60	602,000
57.122 HAI Progress Report State Health Department Survey	55	1	28/60	26
57.123 Antimicrobial Use and Resistance (AUR)—Microbiology Data Electronic Upload Specification Tables	2,500	12	5/60	2,500
57.124 Antimicrobial Use and Resistance (AUR)—Pharmacy Data Electronic Upload Specification Tables	2,500	12	5/60	2,500
57.125 Central Line Insertion Practices Adherence Monitoring	500	213	25/60	44,375
57.126 MDRO or CDI Infection Form	720	11	30/60	3,960
57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	5,500	29	15/60	39,875
57.128 Laboratory-identified MDRO or CDI Event	4,800	79	20/60	126,400
57.129 Adult Sepsis	50	250	25/60	5,208
57.135 Late Onset Sepsis/Meningitis Denominator Form: Data Table for monthly electronic upload	300	6	5/60	150
57.136 Late Onset Sepsis/Meningitis Event Form: Data Table for Monthly Electronic Upload	300	6	5/60	150
57.137 Long-Term Care Facility Component—Annual Facility Survey	17,700	1	120/60	35,400
57.138 Laboratory-identified MDRO or CDI Event for LTCF	1,998	24	20/60	15,984
57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	1,998	12	20/60	7,992
57.140 Urinary Tract Infection (UTI) for LTCF	339	36	35/60	7,119
57.141 Monthly Reporting Plan for LTCF	2011	12	5/60	2,011
57.142 Denominators for LTCF Locations	339	12	35/60	2,373
57.143 Prevention Process Measures Monthly Monitoring for LTCF	130	12	5/60	130
57.150 LTAC Annual Survey	620	1	82/60	847
57.151 Rehab Annual Survey	1,340	1	82/60	1,831
57.200 Healthcare Personnel Safety Component Annual Facility Survey ...	50	1	480/60	400
57.204 Healthcare Worker Demographic Data	50	200	20/60	3,333
57.205 Exposure to Blood/Body Fluids	50	50	60/60	2,500
57.206 Healthcare Worker Prophylaxis/Treatment	50	30	15/60	375
57.207 Follow-Up Laboratory Testing	50	50	15/60	625
57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	50	50	10/60	417
57.300 Hemovigilance Module Annual Survey	500	1	85/60	708
57.301 Hemovigilance Module Monthly Reporting Plan	500	12	60/60	6,000
57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	70/60	7,000
57.305 Hemovigilance Incident	500	10	10/60	833

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form number & name	Number of respondents	Number of responses per respondent	Avg. burden per response (hours)	Total burden (hours)
57.306 Hemovigilance Module Annual Survey—Non-acute care facility	500	1	35/60	292
57.307 Hemovigilance Adverse Reaction—Acute Hemolytic Transfusion Reaction	500	4	20/60	667
57.308 Hemovigilance Adverse Reaction—Allergic Transfusion Reaction ..	500	4	20/60	667
57.309 Hemovigilance Adverse Reaction—Delayed Hemolytic Transfusion Reaction	500	1	20/60	167
57.310 Hemovigilance Adverse Reaction—Delayed Serologic Transfusion Reaction	500	2	20/60	333
57.311 Hemovigilance Adverse Reaction—Febrile Non-hemolytic Transfusion Reaction	500	4	20/60	667
57.312 Hemovigilance Adverse Reaction—Hypotensive Transfusion Reaction	500	1	20/60	167
57.313 Hemovigilance Adverse Reaction—Infection	500	1	20/60	167
57.314 Hemovigilance Adverse Reaction—Post Transfusion Purpura	500	1	20/60	167
57.315 Hemovigilance Adverse Reaction—Transfusion Associated Dyspnea	500	1	20/60	167
57.316 Hemovigilance Adverse Reaction—Transfusion Associated Graft vs. Host Disease	500	1	20/60	167
57.317 Hemovigilance Adverse Reaction—Transfusion Related Acute Lung Injury	500	1	20/60	167
57.318 Hemovigilance Adverse Reaction—Transfusion Associated Circulatory Overload	500	2	20/60	333
57.319 Hemovigilance Adverse Reaction—Unknown Transfusion Reaction	500	1	20/60	167
57.320 Hemovigilance Adverse Reaction—Other Transfusion Reaction	500	1	20/60	167
57.400 Outpatient Procedure Component—Annual Facility Survey	700	1	10/60	117
57.401 Outpatient Procedure Component—Monthly Reporting Plan	700	12	15/60	2,100
57.402 Outpatient Procedure Component Same Day Outcome Measures	200	1	40/60	133
57.403 Outpatient Procedure Component—Monthly Denominators for Same Day Outcome Measures	200	400	40/60	53,333
57.404 Outpatient Procedure Component—SSI Denominator	700	100	40/60	46,667
57.405 Outpatient Procedure Component—Surgical Site (SSI) Event	700	5	40/60	2,333
57.500 Outpatient Dialysis Center Practices Survey	7,200	1	12/60	1,440
57.501 Dialysis Monthly Reporting Plan	7,200	12	5/60	7,200
57.502 Dialysis Event	7,200	30	25/60	90,000
57.503 Denominator for Outpatient Dialysis	7,200	30	10/60	36,000
57.504 Prevention Process Measures Monthly Monitoring for Dialysis	1,730	12	75/60	25,950
57.505 Dialysis Patient Influenza Vaccination	615	50	10/60	5,125
57.506 Dialysis Patient Influenza Vaccination Denominator	615	5	10/60	513
57.507 Home Dialysis Center Practices Survey	430	1	30/60	215
Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Non-Long-Term Care Facilities	125	52	60/60	6,500
Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Long-Term Care Facilities	1,200	52	60/60	62,400
Weekly Resident Influenza Vaccination Cumulative Summary for Long-Term Care Facilities	2,500	52	60/60	130,000
Annual Healthcare Personnel Influenza Vaccination Summary	5,000	1	120/60	10,000
Total				1,718,591

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.

[FR Doc. 2021–20846 Filed 9–24–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Clinical Laboratory Improvement Advisory Committee (CLIAC)

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking nominations for membership on the CLIAC. The CLIAC consists of 20 experts including the Chair, represents

a diverse membership across laboratory specialties, professional roles (laboratory management, technical specialists, physicians, nurses) and practice settings (academic, clinical, public health), and includes a consumer representative.

DATES: Nominations for membership on CLIAC must be received no later than March 1, 2022. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be mailed to Nancy Anderson, MMSc, MT(ASCP), CLIAC Secretary, Senior Advisor for Clinical Laboratories, Division of Laboratory Systems, Center

for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24-3, Atlanta, Georgia 30329-4018, Telephone: (404) 498-2741; or via email at CLIAAC@cdc.gov.

FOR FURTHER INFORMATION CONTACT:

Heather Stang, MS, Deputy Chief, Quality and Safety Systems Branch, Division of Laboratory Systems, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24-3, Atlanta, Georgia 30329-4018, Telephone: (404) 498-2769; HStang@cdc.gov.

SUPPLEMENTARY INFORMATION: The Committee includes three ex officio members (or designees), including the Director, CDC; the Administrator, Centers for Medicare & Medicaid Services (CMS); and the Commissioner, Food and Drug Administration (FDA). A nonvoting representative from the Advanced Medical Technology Association (AdvaMed) serves as the industry liaison. The Designated Federal Official (DFO) or their designee and the Executive Secretary are present at all meetings to ensure meetings are within applicable statutory, regulatory, and HHS General Administration manual directives.

Nominations are being sought for individuals who have the expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. Nominees will be selected based on expertise in the fields of microbiology (including bacteriology, mycobacteriology, mycology, parasitology, and virology), immunology (including histocompatibility), chemistry, hematology, pathology (including histopathology and cytology), or genetic testing (including cytogenetics); from representatives in the fields of medical technology, bioinformatics, public health, and clinical practice; and from consumer representatives. Federal employees will not be considered for membership. Members may be invited to serve for up to four-year terms.

Selection of members is based on candidates' qualifications to contribute to the accomplishment of CLIAAC objectives (<https://www.cdc.gov/cliac/>).

The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented, and the committee's function. Appointments shall be made without discrimination

on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees (SGEs), requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for CLIAAC membership each year and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in July, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year. Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address).

- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. (Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (e.g., CDC, NIH, FDA, etc.).

Nominations may be submitted by the candidate, or by the person/organization recommending the candidate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021-20925 Filed 9-24-21; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-21IE; Docket No. CDC-2021-0103]

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 Understanding Health System Approaches to Chronic Pain Management. The proposed study is designed to evaluate the effects of evidence-based guidelines related to chronic pain management and opioid prescribing.

DATES: CDC must receive written comments on or before November 26, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0103 by any of the following methods:

- *Federal eRulemaking Portal:* [Regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, 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](https://www.regulations.gov).

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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;
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; and
5. Assess information collection costs.

Proposed Project

Understanding Health System Approaches to Chronic Pain Management—New—National Center for Injury Prevention and Control

(NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC requests OMB approval for three years for this new data collection. This study will evaluate the effects of evidence-based guidelines related to chronic pain management and opioid prescribing, including access to medications for opioid use disorder (MOUD) for patients and clinicians in primary care settings among a diverse sample of health systems.

Since 1999, nearly 841,000 people have died from drug overdose in the United States. Over 70% of drug overdose deaths in 2019 involved an opioid. From 1999 to 2019, nearly 247,000 people died in the United States from overdoses involving prescription opioids, with rates of deaths involving prescription opioids more than quadrupling from 1999 to 2019. In response, a range of clinical practice guidelines, policies, and regulations have been released in recent years to address the opioid overdose epidemic, with the goals of supporting safer opioid prescribing, improving diagnosis and treatment of OUD, and reducing overdose deaths in the United States.

To design this evaluation, we previously conducted and completed a “Feasibility Assessment of Health Systems” via surveys to determine the range of policies and guidelines being implemented by health systems, followed by an “evaluability assessment” by means of interviews with leaders of nine health systems. For the purposes of this evaluation, “Chronic pain management policies/guidelines” refers to policies/guidelines that may include prescribing of opioid medications, nonpharmacologic therapies, and/or non-opioid medications for chronic pain, as well as OUD assessment and treatment.

In early 2020, CDC requested OMB approval for a Feasibility Assessment of Health Systems (“Feedback on the use of the CDC Guideline for Prescribing

Opioids for Chronic Pain”) through the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB Control No. 0920–1050). This brief eligibility assessment consisting of surveys was sent to approximately 250 health systems to understand the landscape of health systems and the types of guidelines or policies implemented, and what strategies were used to do so. Of 250 health systems contacted, 46 responded and were considered for the following preliminary phase—the evaluability assessment.

The purpose of this data collection effort is to: (1) Obtain an enhanced understanding of facilitators and barriers to guideline-concordant management of chronic pain and opioid prescribing (including access to MOUD) at the health system level, in order to improve patient outcomes while maximizing patient safety and to facilitate uptake by clinicians and health systems, (2) describe unintended benefits and consequences to guideline/policy implementation, and (3) identify racial and ethnic disparities in guideline/policy implementation.

This mixed-methods, pre-post evaluation of health systems’ implementation of chronic pain management and opioid prescribing policies/guidelines, and the resultant outcomes requires both primary data collection (such as surveys, key informant interviews, focus groups, etc.), and secondary data collection (such as administrative, EHR, pharmacy dispensing, prescribing data, etc.) efforts to adequately answer the research questions. While secondary data (QI measures) from health system EHRs will provide longitudinal pre-post measures, primary data is needed to understand the characteristics and mechanisms of practice and patient change that can be attributed to the policies and guidelines.

The total burden is estimated to be 577 hours annually. There are no direct costs to respondents other than their time to participate in the study.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Patient	Patient Survey	667	1	10/60	111
Treatment facility staff (Including primary care clinicians, health system leaders, and other system staff and representatives).	Primary Care Clinician Survey	1,313	1	10/60	219
	Invitation/Follow up Email	1,980	2	3/60	198
	Health System Leaders Group Interview Guide.	17	1	1	17
	Case Study Interview Guide	30	1	30/60	15

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
	Member Checking (Validation) Sessions Interview Guide.	17	1	1	17
Total					577

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.

[FR Doc. 2021–20843 Filed 9–24–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–21–1014; Docket No. CDC–2021–0099]

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 an existing information collection project titled the CDC Worksite Health Scorecard. The collection is an organizational assessment and planning tool designed to help employers identify gaps in their health promotion programs and prioritize high-impact strategies for health promotion at their worksites.

DATES: CDC must receive written comments on or before November 26, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0099 by any of the following methods:

- **Federal eRulemaking Portal:** *Regulations.gov*. Follow the instructions for submitting comments.

- **Mail:** Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600

Clifton Road NE, MS H21–8, 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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, 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;

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; and

5. Assess information collection costs.

Proposed Project

CDC Worksite Health ScoreCard (CDC ScoreCard) (OMB Control No. 0920–1014, Exp. 3/31/2022)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In the United States, chronic diseases such as heart disease, obesity, and diabetes are among the leading causes of death and disability. Although chronic diseases are among the most common and costly health problems, they are also among the most preventable. Adopting healthy behaviors—such as eating nutritious foods, being physically active, and avoiding tobacco use—can prevent the devastating effects and reduce the rates of these diseases.

Employers are recognizing the role they can play in creating healthy work environments and providing employees with opportunities to make healthy lifestyle choices. To support these efforts, the Centers for Disease Control and Prevention (CDC) developed an online organizational assessment tool called the CDC Worksite Health Scorecard.

The CDC Worksite Health Scorecard is a tool designed to help employers assess whether they have implemented evidence-based health promotion interventions or strategies in their worksites to prevent heart disease, stroke, and related conditions such as hypertension, diabetes, and obesity. The assessment contains 151 core yes/no questions with an additional 20 optional demographic questions divided into 19

modules (risk factors/conditions/demographics) that assess how evidence-based health promotion strategies are implemented at a worksite. These strategies include health promoting counseling services, environmental supports, policies, health plan benefits, and other worksite programs shown to be effective in preventing disease and promoting healthy lifestyles for employees. Employers can use this tool to assess how a comprehensive health promotion and disease prevention program is offered to their employees, to help identify program gaps, and to prioritize high-impact health promotion strategies to be incorporated into their programs.

This is an Extension Information Collection Request (ICR) enabling existing users, as well as new users to continue to have access to the CDC ScoreCard, a web-based organizational assessment tool designed to help

employers identify gaps in their health promotion programs and prioritize high-impact strategies for health promotion at their worksites (available at <http://www.cdc.gov/healthscorecard>).

CDC ScoreCard users will create a user account, complete the online assessment, and receive an immediate feedback report that summarizes the current status of their worksite health program; identifies gaps in current programming; benchmarks individual employer results against other users of the system; and provides access to worksite health tools and resources to address employer gaps and priority program areas. To realize the full benefit of the tool, employers are encouraged to reassess their progress on an annual basis and track improvements over time. CDC will continue to provide outreach to and to register approximately 800 employers per year to use the online survey CDC ScoreCard in their

workplace health program assessment, planning, and implementation efforts. CDC Scorecard is open to employers of all sizes, industry sectors, and geographic locations across the country.

CDC will continue to use the information gathered from the Scorecard to provide better technical assistance, training, and support to employers seeking guidance on building or maintaining workplace health promotion programs including tool and resource development for program planning, implementation, and evaluation related to the CDC ScoreCard's strategies.

OMB approval is requested for three years. CDC requests approval for an estimated 1,000 burden hours annually. Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden (in hrs)
Employers	CDC Worksite Health Scorecard	800	1	75/60	1,000
Total					1,000

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021-20847 Filed 9-24-21; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Interagency Committee on Smoking and Health (ICSH)

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking nominations for membership on the ICSH. The ICSH consists of five public members, as deemed by statute, that represent private entities involved in informing the public about the health effects of smoking.

DATES: Nominations for membership on the ICSH must be received no later than October 22, 2021. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be emailed to Jade Chambers Blair, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), CDC, to JChambersBlair@cdc.gov.

FOR FURTHER INFORMATION CONTACT:

Kathy Gallagher, Designated Federal Official, ICSH, Office on Smoking and Health, NCCDPHP, CDC, 1600 Clifton Road NE, Atlanta, Georgia 30329-4027, Telephone: (404) 639-6358, or email at KGallagher@cdc.gov.

SUPPLEMENTARY INFORMATION:

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. Nominees will be selected based on expertise in the fields of the health effects of smoking. Additionally, desirable qualifications include: (1) Knowledge of evidence based and emerging commercial tobacco control policies as well as experience in analyzing, evaluating, and interpreting Federal, State and/or local health or regulatory policy; and/or (2) familiarity and expertise in developing or contributing to the development of policies and/or programs to advance health equity by identifying and

eliminating commercial tobacco product related inequities and disparities; (3) knowledge of the intersection of behavioral health conditions (mental health and/or substance use disorders) and commercial tobacco use/tobacco control and/or (4) familiarity and expertise with the treatment of commercial tobacco use and dependence, particularly with respect to developing or contributing to interventions for reducing tobacco-related disparities and inequities in the United States. Federal employees will not be considered for membership. Members may be invited to serve for four-year terms.

Selection of members is based on candidates' qualifications to contribute to the accomplishment of ICSH objectives <https://www.cdc.gov/tobacco/about/icsh/index.htm>.

The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented, and the committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens,

and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for ICSH membership each year and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in July 2022, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year.

Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address).
- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. (Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (e.g., CDC, NIH, FDA, etc.).

Nominations may be submitted by the candidate him- or herself, or by the person/organization recommending the candidate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

*Director, Strategic Business Initiatives Unit,
Office of the Chief Operating Officer, Centers
for Disease Control and Prevention.*

[FR Doc. 2021–20920 Filed 9–24–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3412–FN]

Medicare Program; Application by the American Diabetes Association (ADA) for Continued CMS Approval of Its Diabetes Outpatient Self-Management Training Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the American Diabetes Association (ADA) application for continued recognition as a national accrediting organization (AO) for accrediting entities that wish to furnish diabetes outpatient self-management training services to Medicare beneficiaries.

DATES: This final notice is effective on September 27, 2021 through September 27, 2027.

FOR FURTHER INFORMATION CONTACT:

Shannon Freeland, (410) 786–4348.
Caroline Gallaher, (410) 786–8705.
Lillian Williams, (410) 786–8636.

SUPPLEMENTARY INFORMATION:

I. Background

Diabetes outpatient self-management training services are defined at section 1861(qq)(1) of the Social Security Act (the Act) as “educational and training services furnished (at such times as the Secretary determines appropriate) to an individual with diabetes by a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described in paragraph (2)(B), but only if the physician who is managing the individual’s diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual’s diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual’s condition.”

In addition, section 1861(qq)(2)(A) of the Act describes a “certified provider” as a physician, or other individual or entity designated by the Secretary of the Department of Health and Human Services (the Secretary), that, in addition to providing diabetes outpatient self-management training services, provides other items or

services for which payment may be made under this title. Section 1861(qq)(2)(B) of the Act further specifies that a physician, or such other individual or entity, must meet the quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by such Board or is recognized by an organization that represents individuals (including individuals under this title) with diabetes as meeting standards for furnishing the services.

Section 1865 of the Act also permits the Secretary to use accrediting bodies to determine whether a provider entity meets Medicare regulatory quality standards, such as those established for diabetes outpatient self-management training programs. These accrediting bodies determine whether a diabetes outpatient self-management training supplier meets the Medicare regulatory quality standards established for diabetes outpatient self-management training service programs. A national accrediting organization (AO) must be approved by the Centers for Medicare & Medicaid Services (CMS) and meet the standards and requirements specified in 42 CFR part 410, subpart H, to qualify for Medicare deeming authority.

Our regulations regarding the application procedures for diabetes outpatient self-management training AOs seeking CMS approval are set forth at 42 CFR 410.142. A national accreditation organization applying for deeming authority must provide CMS with reasonable assurance that it will require the diabetes outpatient self-management training suppliers it accredits to meet the CMS quality standards, the National Standards for Diabetes Self-Management Education and Support (NSDSMES) standards, or an alternative set of standards that meet or exceed our requirements that have been developed by that AO and that have been approved by CMS (see 42 CFR 410.144).

Section 410.142(a) of our regulations states that “CMS may approve and recognize a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish training.” Therefore, all diabetes outpatient self-management training AOs must be not-for-profit organizations.

Section 410.142(b) of our regulations require a diabetes outpatient self-management training AO to submit specific documents and information with their application, as discussed in section II of this final notice.

II. Provisions of the Proposed Notice

On April 27, 2021, we published a proposed notice in the **Federal Register** (86 FR 22211) acknowledging receipt of the American Diabetes Association's (ADA's) request for continued CMS approval of its diabetes outpatient self-management training accreditation program. In that proposed notice, we detailed our evaluation criteria.

Under section 1861(qq) of the Act and our regulations at § 410.142, we conducted a review of the ADA's diabetes outpatient self-management training program application using the criteria specified by our regulations, which include authorization for CMS to conduct an onsite visit to verify information in the organization's application. For an onsite visit, the CMS review team travels to the AO's corporate office to review specific information and documents. An onsite visit is typically part of every application review. However, due to the COVID-19 pandemic, it was not possible for us to conduct an onsite visit for the ADCES. We conducted our review virtually, using remote means to access and review the necessary information. During this virtual review, we reviewed documentation including the ADA's: (1) Corporate policies; (2) financial and human resources records; (3) policies and procedures, including those for training, monitoring, and evaluation of its surveyors and investigating and responding appropriately to complaints against accredited diabetes outpatient self-management training suppliers; and (4) survey review and decision-making process for accreditation. This is the same information that would have been reviewed during an onsite visit.

Also, as part of the ADA's application review, we reviewed and assessed the following documents submitted by the ADA:

- A detailed comparison including a crosswalk between the organization's standards and the CMS quality standards described in § 410.144(a).
- Detailed information about the organization's accreditation process, including all of the following information:

- ++ Frequency of accreditation.
- ++ Copies of accreditation forms, guidelines, and instructions to evaluators.

- ++ Descriptions of the following:
 - The accreditation review process and the accreditation status decision making process.
 - The procedures used to notify a deemed entity of deficiencies in its diabetes outpatient self-management training program and procedures to monitor the correction of those deficiencies.
 - The procedures used to enforce compliance with the accreditation requirements and standards.
 - Detailed information about the individuals who perform evaluations for the organization, including all of the following information:
 - ++ The education and experience requirements for the individuals who perform evaluations.
 - ++ The content and frequency of continuing education furnished to the individuals who perform evaluations.
 - ++ The process used to monitor the performance of individuals who perform evaluations.
 - ++ The organization's policies and practices for participation in the accreditation process by an individual who is professionally or financially affiliated with the entity being evaluated.
 - A description of the organization's data management and analysis system for its accreditation activities and decisions, including the kinds of reports, tables, and other displays generated by that system.
 - A description of the organization's procedures for responding to and investigating complaints against an approved entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and CMS.
 - A description of the organization's policies and procedures for withholding or removing a certificate of accreditation for failure to meet the organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.
 - A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that will serve as a basis for accreditation if CMS approves the organization.
 - A list of all of the approved entities currently accredited to furnish training and the type, category, and expiration date of the accreditation held by each of them.

- The name and address of each person with an ownership or control interest in the organization.
- Documentation that demonstrates its ability to furnish CMS with electronic data in CMS-compatible format.
- A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required accreditation activities.
- A statement acknowledging that, as a condition for approval and recognition by CMS of its accreditation program, it agrees to comply with the requirements set forth in §§ 410.142 through 410.146.
- Any additional information CMS requests to enable it to respond to the organization's request for CMS approval and recognition of its accreditation program to accredit entities to furnish training.

The April 27, 2021, proposed notice also solicited public comment regarding whether the ADA's requirements meet or exceed the NSDSMES, which are the accreditation standards used for accreditation of diabetes outpatient self-management training programs accredited by the ADA, pursuant to § 410.144(b) and § 410.142(e)(1).

III. Analysis of and Responses to Public Comments on the Proposed Notice

CMS received three comments in response to the April 27, 2021 proposed notice; however, only one of these comments were within the scope of the comment solicitation.

The comment and our response is addressed below.

Comment: One commenter stated that diabetes outpatient self-management training, also sometimes referred to as diabetes self-management education and support is an evidence-based vital service for people who have been diagnosed with diabetes, that has been proven to enhance their clinical outcomes. The commenter also stated "wholehearted" support for the application submitted by the ADA for continued CMS recognition as a national AO for diabetes outpatient self-management training programs. The commenter further stated the belief that "it is imperative that the ADA continue to offer its services as an AO for outpatient self-management training suppliers."

Response: We thank the commenter for their support of the CMS diabetes outpatient self-management training program and for their recommendation for the approval of the ADA's application.

IV. Provisions of the Final Notice

A. Comparison of the ADA's Standards and Requirements for Accreditation to the NSDSMES and the Medicare Application Requirements

We compared the ADA's diabetes outpatient self-management training accreditation requirements and survey process with the NSDSMES requirements and CMS application requirements in 42 CFR part 410, subpart H, as described in section II of this final notice.

We found the ADA's accreditation standards and process to be consistent with the NSDSMES standards and CMS requirements.

B. Term of Approval

Based on the review and observations described in section II of this final notice, we have determined that the ADA's requirements for diabetes outpatient self-management training meet our requirements. Therefore, we approve the ADA as a national accreditation organization for diabetes outpatient self-management training program that request participation in the Medicare program, effective September 27 2021 through September 27, 2027.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: September 22, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–20943 Filed 9–24–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Performance Review Board Membership

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice of performance review board membership.

5 U.S.C. 4314(c)(1) through (5) requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more Senior Executive Service (SES) Performance Review Boards (PRBs).

The PRB shall review and evaluate the initial summary rating of a senior executive's performance, the executive's response, and any higher-level review's comments on the initial summary rating. In addition, the PRB will review and recommend executive performance bonuses and pay increases.

5 U.S.C. 4314(c)(4) requires the appointment of board members to be published in the **Federal Register**. The following persons comprise a standing roster to serve as members of the SES PRB for the Centers for Medicare & Medicaid Services:

Jonathan Blum, Principal Deputy Administrator and Chief Operating Officer (serves as the Chair)
Tia Butler, Director, Office of Human Capital (serves as the Co-chair)
Elizabeth Fowler, Deputy Administrator and Director, Center of Medicare
Arielle Woronoff, Director, Office of Legislation
Karen Jackson, Deputy Chief Operating Officer
Elizabeth Richter, Deputy Center Director, Center for Medicare
Karen Shields, Deputy Center Director, Center for Medicaid and CHIP Services
Arrah Tabe-Bedward, Deputy Director, Center for Medicare and Medicaid Innovation
Jeffrey Wu, Deputy Director for Operations, Center for Consumer Information and Insurance Oversight

The Principal Deputy Administrator and Chief Operating Officer of the Centers for Medicare & Medicaid Services (CMS), Jonathan Blum, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Kathy Vaughn, 410–786–1050 or katherine.vaughn@cms.hhs.gov.

Vanessa Garcia,

Federal Register Liaison.

[FR Doc. 2021–20886 Filed 9–24–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Administration and Oversight of the Unaccompanied Children Program (OMB #0970–0547)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is inviting public comments on revisions to an approved information collection. The request consists of several forms that allow the Unaccompanied Children (UC) Program to monitor care provider facility compliance with federal laws and regulations, legal agreements, and ORR policies and procedures; and perform other administrative tasks.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: ORR received several comments on this information collection in response to the **Federal Register** Notice published on January 6, 2021, (86 FR 545) and has provided responses to those comments in its final submission to OMB. UC Path is critical to program operations and it is

important that rollout of the new system not be delayed. Therefore, the below description details what will be included in the initial launch of the UC Path case management system and revisions based on public comments will be made after initial launch. ORR plans to conduct a deliberative review of commenters' suggestions and concerns and submit a request for revisions to this information collection request in January 2022. The upcoming information collection request will also include revisions based on feedback from UC Path system users (*i.e.*, ORR grantee, contractor, and federal staff).

A. ORR plans to revise six instruments currently approved under OMB #0970-0547. Four of the revised instruments will be incorporated into ORR's new case management system, UC Path. The other two revised instruments are and will remain PDF instruments. In addition, ORR plans to add four new instruments to this collection—two will be incorporated into UC Path and two will be in PDF format. ORR also plans to remove one currently approved instrument from this collection. Finally, ORR plans to replace the term “unaccompanied alien child (UAC)” with “unaccompanied child (UC)” throughout the instruments in this collection.

1. Care Provider Facility Tour Request (Form A-1A): This instrument is used by advocacy groups, faith-based organizations, researchers, government officials, and other stakeholders to request tours of ORR care provider facilities. After the request is received, ORR documents its decision and details regarding date and location of the tour, if applicable, and provides the completed form to the requester. No revisions are currently requested; ORR plans to continue use of this form as-is.

2. Notice to UC for Flores Visits (Forms A-4 & A-4s): This instrument is used by care provider facilities to notify UC of upcoming visits by *Flores* counsel (lawyers and volunteers from the organization that originally participated in the creation of the Flores Settlement Agreement) and allows UC to add their name to a sign-up sheet if they are willing to speak with *Flores* counsel. ORR updated the Spanish translation of this PDF instrument.

3. Authorization for Release of Records (Form A-5): This instrument is used by attorneys, legal service providers, government agencies, and other stakeholders to request UC case file records. In most cases, requesters are required to obtain the signature of the subject of the record request (UC or their parent/legal guardian or sponsor)

and a witness. ORR made the following revisions:

- Added a section in which ORR-funded legal service providers are required to certify their representation of the child.

- Added a separate area where sponsors may authorize the release of their records.

- Updated the required supporting documentation for a representative of a federal/state government agency or the National Center for Missing and Exploited Children to further require that the requester specify the scope of their investigation and provide a case reference number.

- Clarified in the instructions that ORR will not release any records that are clearly outside of the scope of a government agency's investigation absent a court-issued subpoena or order.

4. Notification of Concern (Form A-7): This instrument is used by home study and post-release service caseworkers, care provider case managers, and the ORR National Call Center to notify ORR of certain concerns that arise after a UC is released from ORR custody. This is a new instrument that ORR plans to add to this collection.

5. Event (Form A-9): This instrument is used by ORR care provider programs to document high-level information about situations that must be reported to ORR. Creating an *Event* is the first step in creating any type of incident report (see forms A-10A to A-10C below), *PLE Report* (see form A-10D below), or *Notification of Concern* (see form A-7 above). After an *Event* is created, an incident report or *Notification of Concern* is created for each UC involved in the incident and linked to the *Event*. For program-level events, one *PLE Report* is created and linked to the *Event*. *Event* information is visible in each individual report/notification report. This instrument was previously approved as part of ORR's various incident reports (Forms A-10A to A-10D). ORR is listing it separately, as a new instrument, to better align instruments in this collection with how data will be entered in UC Path. Some fields that were previously entered in each incident report have been moved into this instrument so that they only need to be entered once. The form also contains several new fields that capture additional information about the location and timeframe of the event. Please note that internal form number A-9 was previously assigned to the Program-Level Event Report.

6. Emergency Significant Incident Report (SIR) and Addendum (Form A-10A): This instrument is used by ORR care provider programs to inform ORR

of urgent situations in which there is an immediate threat to a child's safety and well-being that require instantaneous action. In some cases, an Emergency SIR Addendum may be required to provide additional information obtained after the initial report. ORR made the following revisions:

- Revised the available options for the category and subcategory fields.

- Added fields to capture additional detail on individuals involved in the incident, actions taken, and video footage.

- Added fields to capture additional information related to reporting of incidents to child protective services, state licensing agencies, and local law enforcement.

- Added a disposition field to indicate whether the incident is closed or if the incident is open and further action is required.

- Updated functionality for the list of individuals who need to be notified of the incident so that it is auto-populated and notification emails can be sent from within the UC Path system.

- Updated internal form numbering so that reports and addendums fall under the same form number.

7. Significant Incident Report (SIR) and Addendum (Form A-10B): This instrument is used by ORR care provider programs to inform ORR of situations that affect, but do not immediately threaten, the safety and well-being of a child. In some cases, an SIR Addendum may be required to provide additional information obtained after the initial report. ORR made the following revisions:

- Revised the available options for the category and subcategory fields.

- Added fields to capture additional detail on individuals involved in the incident, actions taken, and video footage.

- Added fields to capture additional information related to reporting of incidents to child protective services, state licensing agencies, and local law enforcement.

- Added a disposition field to indicate whether the incident is closed or if the incident is open and further action is required.

- Updated functionality for the list of individuals who need to be notified of the incident so that it is auto-populated and notification emails can be sent from within the UC Path system.

- Updated internal form numbering so that reports and addendums fall under the same form number.

8. Sexual Abuse Significant Incident Report (SA/SIR) and Addendum (Form A-10C): This instrument is used by ORR care provider programs to inform ORR

of allegations of sexual harassment, sexual abuse, and inappropriate sexual behavior that occurred while the UC was in ORR custody. In some cases, an SA/SIR Addendum may be required to provide additional information obtained after the initial report. ORR made the following revisions:

- Revised the available options for the category and subcategory fields.
- Added fields to capture additional detail on individuals involved in the incident, actions taken, and video footage.

- Added fields to capture additional information related to reporting of incidents to child protective services, state licensing agencies, and local law enforcement.

- Added a disposition field to indicate whether the incident is closed or if the incident is open and further action is required.

- Updated functionality for the list of individuals who need to be notified of the incident so that it is auto-populated and notification emails can be sent from within the UC Path system.

- Updated internal form numbering so that reports and addendums fall under the same form number.

9. Program-Level Event (PLE) Report and Addendum (Form A-10D): This instrument is used by ORR care provider programs to inform ORR of events that may affect the entire care provider facility, such as an active shooter or natural disaster. An updated PLE Report is required for events that occur over multiple days or if the situation changes regarding the event. ORR made the following revisions:

- Revised the available options for the category and subcategory fields.

- Added fields to capture additional detail on individuals involved in the incident, actions taken, and video footage.

- Added fields to capture additional information related to reporting of incidents to child protective services, state licensing agencies, and local law enforcement.

- Added a disposition field to indicate whether the incident is closed or if the incident is open and further action is required.

- Updated functionality for the list of individuals who need to be notified of the incident so that it is auto-populated and notification emails can be sent from within the UC Path system.

- Updated internal form numbering so that reports and addendums fall under the same form number.

10. Hotline Alert (Form A-12): ORR is discontinuing this instrument. In UC Path, the ORR National Call Center will use the Notification of Concern instead of the Hotline Alert.

11. Key Personnel Minimum Qualifications Checklist and Attestation (Form A-14): This instrument is used by ORR care provider programs to request hiring approval for key positions, as required in the ORR cooperative agreement, and, if applicable, request a waiver of minimum qualifications when appropriately justified. This is a new instrument that ORR plans to add to this collection and is currently approved under OMB #0970-0558.

12. ORR Waiver Request (Form A-15): This instrument is used by ORR care provider programs to request a waiver of a permissible regulatory, policy, procedure, or cooperative agreement requirement. ORR considers waiver requests when appropriately justified and when the safety and well-being of children in ORR custody would not be adversely affected. ORR does not have the authority to waive federal or state statute or state regulations and may only waive certain provisions of federal regulations where specified by the

regulation. This is a new instrument that ORR plans to add to this collection and is currently approved under OMB #0970-0558.

B. ORR plans to remove the term “alien” from the title of this information collection and revise it to read “Administration and Oversight of the Unaccompanied Children Program.”

C. ORR intends to conduct a phased rollout of the UC Path system. Beginning fall 2021, ORR plans to roll the UC Path system out to a small group of care provider programs. ORR will gradually expand use of the system to other programs and expects all care provider programs will be using UC Path by spring 2022. To ensure continuity of operations, care provider programs will need the ability to continue using instruments in the UC Portal system while they are waiting to transition over to the UC Path system. Therefore, ORR proposes continued use of the following UC Portal (ORR’s current case management system) instruments, concurrently with the UC Path versions of the same instruments, until all care provider programs are using UC Path.

- Emergency Significant Incident Report and Addendum (Form A-10A)
- Significant Incident Report and Addendum (Form A-10B)
- Sexual Abuse Significant Incident Report and Addendum (Form A-10C)
- Program-Level Event Report and Addendum (Form A-10D)

Respondents: ORR grantee and contractor staff; advocacy groups, faith-based organizations, researchers, and government officials; attorneys, legal service providers, child advocates, and government agencies; and other stakeholders.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden minutes per response	Annual total burden hours
Respondents				
Care Provider Facility Tour Request (Form A-1A)	200	1	10	33
Notice to UC for Flores Visits (Forms A-4 & A-4s)	20	1	15	5
Authorization for Release of Records (Form A-5)	4,000	1	15	1,000
Notification of Concern (Form A-7)	60	75	15	1,125
Event (Form A-9)	276	160	10	7,360
Emergency Significant Incident Report and Addendum (Form A-10A) ..	216	14	60	3,024
Significant Incident Report and Addendum (Form A-10B)	216	491	60	106,056
Sexual Abuse Significant Incident Report and Addendum (Form A-10C)	216	47	60	10,152
Program Level Event (Form A-10D)	216	7	60	1,512
Key Personnel Minimum Qualifications Checklist and Attestation (Form A-14)	235	9	10	353
ORR Waiver Request (Form A-15)	235	2	20	157

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden minutes per response	Annual total burden hours
Estimated Annual Burden Hours Total				130,777
Record Keepers				
Care Provider Facility Tour Request (Form A-1A)	216	1	120	432
Authorization for Release of Records (Form A-5)	216	19	20	1,368
Estimated Annual Burden Hours Total				1,800

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores v. Reno* Settlement Agreement, No. CV85-4544-RJK (C.D. Cal. 1996).

Mary B. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2021-20918 Filed 9-24-21; 8:45 am]

BILLING CODE 4184-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1978-N-0018]

Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use; Over the Counter Monograph Proposed Order; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of an over-the-counter (OTC) monograph proposed order (order ID OTC000008) entitled “Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use.” FDA is issuing this proposed order to amend and revise the deemed final administrative order concerning nonprescription sunscreen drug products (Deemed Final Order) established by the enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). This proposed order, if finalized, would replace the Deemed Final Order in its entirety with new conditions under which nonprescription sunscreen drug products would be determined to be generally recognized as safe and effective (GRASE) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). It also sets forth certain characteristics that would establish that a sunscreen drug product is not GRASE.

DATES: Submit electronic comments on the proposed order by 11:59 p.m. Eastern Time at the end of November 12, 2021.

ADDRESSES: You may submit comments to Order ID OTC000008 as follows. Please note that late, untimely filed comments will not be considered. Comments must be submitted electronically on or before November 12, 2021. The <https://www.regulations.gov> will accept comments at any time until 11:59 p.m. Eastern Time at the end of November 12, 2021.

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 information that you or a third party may not wish to be publicly posted, such as medical information or 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 electronically in the manner detailed in “Instructions.”

Instructions: All submissions received must include the Order ID Number OTC000008 and the Docket No. FDA-1978-N-0018 for “Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use.” Received comments, those

filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” will be publicly viewable on <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**Under section 505G(d) of the FD&C Act (21 U.S.C. 355h(d)), FDA must make any information submitted by any person with respect to this order available to the public upon submission, with limited exceptions. FDA will not make public information pertaining to pharmaceutical quality information, unless such information is necessary to establish standards under which a drug is generally recognized as safe and effective under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)) (see section 505G(d)(2)(B) of the FD&C Act). FDA will also not make public information that is of the type contained in raw datasets (see section 505G(d)(2)(B) of the FD&C Act). To submit a comment with this specific confidential information that you do not wish to be made publicly available, electronically submit two copies of the comment as an attachment to your comment submission. One copy will include the information that 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. The second copy, which will have the claimed information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Any information marked as “confidential” will not be disclosed except in accordance with section 505G(d) of the FD&C Act, and other applicable disclosure law.

Docket: For access to the docket to read background documents or the electronic 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 the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-7945.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an OTC monograph proposed order (order ID OTC000008), issued pursuant to section 505G(b) of the FD&C Act and section 3854(c)(1) of the CARES Act (Pub. L. 116-136), entitled “Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use.” FDA is issuing this proposed order to amend and revise the Deemed Final Order established by the enactment of the CARES Act (March 27, 2020).¹ This proposed order, if finalized, would replace the Deemed Final Order in its entirety with new conditions under which nonprescription sunscreen drug products would be determined to be GRASE under section 201(p)(1) of the FD&C Act. It also sets forth certain characteristics that would establish that a sunscreen drug product is not GRASE under section 201(p)(1) of the FD&C Act.

In February 2019, FDA issued a proposed rule entitled “Sunscreen Drug Products for Over-the-Counter Human Use” (2019 Proposed Rule).² The 2019 Proposed Rule proposed to amend the sunscreen monograph regulation then codified in 21 CFR part 352, which had been stayed since its 1999 issuance, and to put into effect a final monograph for sunscreens.³ The 2019 Proposed Rule

included proposals related to sunscreen active ingredients, maximum sun protection factor (SPF) levels, broad spectrum requirements, dosage forms, labeling, final formulation testing and recordkeeping, sunscreen-insect repellent combinations, and more.

In addition, because the 2019 Proposed Rule identified a need for safety data to support the GRASE status of sunscreens containing certain sunscreen active ingredients—and because FDA expected that the development of these data could take substantially longer than the comment period on the proposed rule—the Agency offered to consider requests to defer further rulemaking on these ingredients while the data were being developed (see 2019 Proposed Rule 84 FR 6204 at 6249). At the end of the comment period on the 2019 Proposed Rule, FDA received a significant number of comments, as well as a request to defer further rulemaking on avobenzone, homosalate, octinoxate, octisalate, octocrylene, oxybenzone, ensulizole, and meradimate while data were being developed to support their GRASE status.

The process for amending the OTC sunscreen monograph was changed by the enactment on March 27, 2020, of section 505G of the FD&C Act, as added by the CARES Act. Among other things, the CARES Act replaced the rulemaking process under which the sunscreen proposed rule had been issued with an administrative order process. In addition, section 505G of the FD&C Act established that, as of the date of enactment of the CARES Act, a sunscreen drug that satisfies certain requirements is deemed to be GRASE and not a new drug. The CARES Act also created a “final administrative order” for sunscreens (the Deemed Final Order) consisting of “the requirements specified in [21 CFR part 352], as published on May 21, 1999 . . . except that the applicable requirements governing effectiveness and labeling [are] those specified in [21 CFR 201.327],” which the statute established as “the applicable requirements in terms of conformity with a final monograph” for these sunscreen drugs.⁴ The CARES

provisions then codified in 21 CFR 201.327, and to new drug regulations.

⁴ This refers to the previously-stayed 1999 final monograph for sunscreens (1999 Final Monograph).

⁵ Section 505G(a)(2) of the FD&C Act. Complementary to these requirements for conformity to the specified final monograph, section 505G also deemed the requirements of certain pre-CARES Act monograph rulemaking documents for drugs described by the sunscreen-specific provisions of section 505G(a)(2), as well as “[r]egulations in effect on the day before the date of the enactment of [section 505G], establishing

Act directs FDA to amend and revise this Deemed Final Order for sunscreens, and requires that the proposed version of this revised sunscreen order be issued not later than 18 months after the enactment of the CARES Act (*i.e.*, by September 27, 2021).⁶ The proposed order that is the subject of this document is being issued consistent with that requirement.

FDA proposes that the conditions laid out in the Deemed Final Order do not ensure that sunscreen drug products are GRASE under section 201(p)(1) of the FD&C Act for the reasons explained in the proposed order. If finalized, the proposed order would replace the Deemed Final Order in its entirety with new conditions under which nonprescription sunscreen drug products would be determined to be GRASE under section 201(p)(1) of the FD&C Act. It also sets forth certain characteristics that would establish that a sunscreen drug product is not GRASE under section 201(p)(1) of the FD&C Act.

In the proposed order, FDA is publishing proposed requirements that are substantively the same as those that the Agency described in the 2019 Proposed Rule, with minor changes, including changes to reflect the enactment of section 505G of the FD&C Act. Similarly, our scientific discussions regarding sunscreens are generally the same as those in the 2019 Proposed Rule. FDA is using this proposed order as a vehicle to efficiently transition its ongoing consideration of the appropriate requirements for OTC sunscreens marketed without approved applications from the previous rulemaking process to the order process created by new section 505G of the FD&C Act.

The 2019 Proposed Rule presented a thorough Agency analysis of publicly available data regarding sunscreens at the time of its issuance. The legal and scientific standards for general recognition of safety and effectiveness underpinning this analysis were not

requirements for specific nonprescription drugs marketed pursuant to [section 505G]” to be final administrative orders under section 505G(b) (see sections 505G(b)(8) and 505G(k)(2) of the FD&C Act). The resulting document (the Deemed Final Order) is available in the in the OTC Monographs@FDA portal at <https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm>.

⁶ See section 3854(c)(1)(B) of the CARES Act. See also section 505G(b)(8) of the FD&C Act (stating that final monograph orders, specifically including the order consisting of the monograph establishing the conditions of use for sunscreen under section 505G(a)(2), can be “amended, revoked, or otherwise modified in accordance with the procedures of [section 505G(b)].”).

¹ To address nonprescription sunscreen drug products that are also subject to provisions in other monographs, this proposed order also proposes to amend and revise “OTC Monograph M016, Skin Protectant Drug Products for Over-the-Counter Human Use,” and to consolidate existing and new provisions that identify sunscreens that are not GRASE in “Non-Monograph Conditions NM020: Sunscreen Drug Products for Over-the-Counter Human Use.”

² The 2019 Proposed Rule (84 FR 6204, February 26, 2019) followed from FDA’s announcement in 2011 that “we are considering certain active ingredient safety issues further. . . . In a forthcoming rulemaking, we intend to request additional data regarding the safety of the individual sunscreen active ingredients” (“Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use,” 76 FR 35672 at 35673, June 17, 2011).

³ These proposals included proposed changes to several related regulations, including labeling

changed by the CARES Act.⁷ We are aware that there have been scientific developments in the time since the proposed rule was issued including, among other things, the publication of two new studies on the absorption of sunscreen active ingredients,⁸ both of which reinforced the need for the sunscreen ingredient data requested in our proposed rule (and in the proposed order). The comment period on this proposed order affords an opportunity for the public to submit information that has become available since the closure of the comment period on the 2019 Proposed Rule. This includes information that has become available regarding the eight sunscreen active ingredients, identified above, that were the subject of timely requests for deferral in order to conduct studies to generate data first identified as lacking in the 2019 Proposed Rule. We note that if at any time the available evidence becomes sufficient to resolve the uncertainty as to the GRASE status of a sunscreen containing any of these ingredients, FDA intends to proceed to a revised final order reflecting our conclusion as to its status. However, if at the close of the comment period on this proposed order, the available data do not resolve the outstanding questions about each of these ingredients, but the Agency has received satisfactory indication of timely and diligent progress on the necessary studies for a specific ingredient, FDA would be prepared to initially defer issuance of a revised final order on the GRASE status of sunscreens containing that particular active ingredient. Such a deferral would be for a period of not more than 1 year, with a possibility of extension depending on further satisfactory progress with the studies. However, if, in FDA's judgment, studies for any active ingredient do not appear to be proceeding in a timely manner or otherwise do not appear to be productive, the Agency expects that it will proceed to a revised final order on sunscreens containing such particular ingredient after this initial deferral.

As noted above, the Agency also received a significant number of comments to the public docket during the previous public comment period on the proposals described in the 2019 Proposed Rule, which we continue to

review. FDA will consider all comments that were submitted to the public docket for the 2019 Proposed Rule within its comment period to be constructively submitted as comments on the proposed order being issued today. To enable the Agency to review and address these comments (and future comments that may be submitted on this proposed order) as expeditiously as possible, we request that commenters do *not* resubmit comments on this proposed order previously submitted on the proposed rule. FDA believes that this approach will allow us to efficiently consider public input as the Agency assesses the appropriate regulatory requirements for nonprescription sunscreens marketed without approved new drug applications.

We emphasize in the proposed order, and here, that the proposed order does not represent a conclusion by FDA that the sunscreen active ingredients included in the 1999 Final Monograph, but proposed in the order as needing additional data, are unsafe for use in sunscreens. Rather, we are requesting additional information on these ingredients so that we can evaluate their GRASE status in light of changed conditions, including substantially increased sunscreen usage and exposure and evolving information about the potential risks associated with these products since originally evaluated. As in the 2019 Proposed Rule, this proposed order also advances proposals addressing the other conditions of use for sunscreen drug products marketed without an approved application, including broad spectrum protection, maximum SPF requirements, dosage forms, labeling, final formulation testing and recordkeeping, sunscreen-insect repellent combinations, and more.

II. Paperwork Reduction Act of 1995

This proposed order is issued under section 505G(b) of the FD&C Act. Chapter 35 of title 44, United States Code does not apply to collections of information made under section 505G of the FD&C Act (see section 505G(o) of the FD&C Act).

III. Electronic Access

Persons may obtain the proposed order at the OTC Monographs portal at <https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm> or at <https://www.regulations.gov>.

IV. References

The following references are on display with the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday

through Friday; these are not available electronically at <https://www.regulations.gov> as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Matta, M.K., J. Florian, R. Zusterzeel et al., "Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial," *Journal of the American Medical Association*, vol. 323(3), pp. 256–267, 2020 (available at <https://jamanetwork.com/journals/jama/fullarticle/2759002>), accessed August 12, 2021.
2. Matta, M.K., R. Zusterzeel, R.P. Nageswara Matta et al., "Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial," *Journal of the American Medical Association*, vol. 321(21), pp. 2082–2091, 2019 (available at <https://jamanetwork.com/journals/jama/fullarticle/2733085>), accessed August 12, 2021.

Dated: September 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20780 Filed 9–24–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Criteria for Determining Maternity Care Health Professional Target Areas

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for public comment.

SUMMARY: In accordance with the requirements of the Public Health Service Act, HRSA, authorized by the Secretary of HHS, shall establish the criteria which will be used to determine maternity care health professional target areas (MCTAs) in existing primary care Health Professional Shortage Areas (HPSAs). This notice sets forth the proposed criteria which will be used to identify and score MCTAs.

DATES: Submit written comments no later than November 26, 2021.

ADDRESSES: Written comments should be submitted to SDMP@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Janelle McCutchen, Chief, Shortage Designation Branch, Division of Policy

⁷ See section 505G(k)(1) of the FD&C Act and 21 CFR 330.10(a)(4).

⁸ See "FDA in Brief: FDA Announces Results From Second Sunscreen Absorption Study," available at <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-announces-results-second-sunscreen-absorption-study>, describing Matta, et al. (2020) (Ref. 1), as well as a prior pilot study (Matta, et al. 2019) (Ref. 2).

and Shortage Designation, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–9156.

SUPPLEMENTARY INFORMATION: Section 332 of the Public Health Service Act, 42 U.S.C. 254e, provides that HRSA shall designate HPSAs based on criteria established by regulation. HPSAs are defined in section 332 to include (1) urban and rural geographic areas which HRSA determines have shortages of health professionals, (2) population groups with such shortages, and (3) public or private medical facilities or other public facilities with such shortages. The required regulations setting forth the criteria for designating HPSAs are codified at 42 CFR part 5.

Section 332(k)(1) provides that HRSA shall identify shortages of maternity care services “within health professional shortage areas.” Section 332(k)(1) further requires HRSA to identify MCTAs and distribute maternity care health professionals within HPSAs using the MCTAs so identified. HRSA must also collect and publish data in the **Federal Register** comparing the availability and need of maternity care health services in HPSAs and must seek input from relevant provider organizations and other stakeholders.

HRSA sought input regarding MCTA scoring from relevant stakeholders via a Request for Information issued in May 2020. HRSA received 24 comments from a variety of stakeholders, including State Primary Care Offices, Indian tribes, Federally Qualified Health Centers, and women’s health and public health advocacy groups. The comments addressed a wide range of maternity care concerns, including social determinants of health that impact maternal health outcomes, women’s access to prenatal care, prevalence of chronic disease, maternity care health professional provider types to be included in MCTAs, and the maternity care needs of women in rural areas and among tribes and Alaska natives. Several commenters also provided suggestions on data sources that HRSA could use to calculate MCTA scores.

HRSA has carefully reviewed and considered all of the feedback provided. HRSA proposes the following MCTA scoring criteria, which will be used to distribute certain currently eligible National Health Service Corps (NHSC) clinicians who provide maternity care services. This includes obstetrician gynecologists (OB/GYNs) and certified nurse midwives (CNMs). The statute does not expand discipline eligibility for participation in the NHSC to health

professionals who are not already eligible for the NHSC. *See* section 332(k)(1).

Approach for Determining Maternity Care Health Professional Target Areas of Greatest Shortage

A MCTA score will be generated for each primary care HPSA using the HPSA’s service area. The following six scoring criteria will be included in a composite scale that will be used to identify MCTAs with the greatest shortage of maternity care health professionals: (1) Ratio of females ages 15–44-to-full time equivalent maternity care health professional ratio; (2) percentage of females 15–44 with income at or below 200 percent of the federal poverty level (FPL); (3) travel time and distance to the nearest provider location with access to comprehensive maternity care services; (4) fertility rate; (5) the Social Vulnerability Index; and (6) four maternal health indicators (pre-pregnancy obesity, pre-pregnancy diabetes, pre-pregnancy hypertension, and prenatal care initiation in the first trimester). Each of these six criteria will be assigned a relative weight based on the significance of that criteria relative to all the others.

The weighted scores will be summed to develop a composite MCTA score ranging from zero to 25, with 25 indicating the greatest need for maternity care health professionals in the MCTA. Accordingly, the higher the composite score, the higher the degree of need for maternity care health services.

Score for Population-to-Full-Time-Equivalent Maternity Care Health Professional Ratio

HRSA is seeking public comment on the proposed approach to measuring the ratio of females ages 15–44-to-full time equivalent (FTE) maternity care health professional, as HRSA received overwhelmingly positive stakeholder feedback indicating that HRSA should consider the population-to-provider ratio as a component of the MCTA score. Accordingly, population-to-provider ratio will measure the number of women of childbearing age in the service area compared to the number of maternity care health professionals in the service area. The population-to-provider ratio continues to be a cornerstone in measuring the availability of primary care resources within a particular area. Based on the available literature and recommendations received, for purposes of MCTA scoring, women of childbearing age will be defined as

women between the ages of 15–44 years old and maternity care professionals will be defined as Obstetrician/Gynecologists and Certified Nurse Midwives (CNMs).¹ A population-to-provider ratio of 1,500:1 will be used as a minimum requirement for a population to be considered reasonably served by Obstetrician/Gynecologists and CNMs.²

Based on comments received, research, and consultation with stakeholders, HRSA did not include General Surgeons, Anesthesiologists, Pediatricians, Doulas, and Lactation Specialists into the provider portion of the population-to-provider ratio for MCTA scoring, as these providers do not typically provide full-scope comprehensive maternity care. Additionally, HRSA considered including Family Medicine Physicians, Physician Assistants, Advance Practice Registered Nurses, and Registered Nurses who provide Women’s Health services or obstetric care into the provider portion of the population-to-provider ratio for MCTA scoring. With respect to Family Medicine Physicians, research shows that family medicine practitioners offering maternity care services has been in decline in recent years, and data demonstrating how much time these providers spend providing maternity care services is not readily available.

Rayburn, Petterson, and Phillips conducted an observational study from 2003 to 2010 in which they examined the proportion of Family Physicians who perform deliveries.³ The proportion of Family Physicians performing deliveries declined by 40.6 percent, from 17.0 percent in 2003 to 10.1 percent in 2009, with deliveries being more common in nonmetropolitan areas. The researchers concluded that the proportion of Family Physicians performing deliveries continues to decline with most delivering Family Physicians performing 25 or fewer deliveries per year. In another study, Makaroff, et al., evaluated factors that are contributing to the decline of Family

¹ Johantgen, M. et al. “Comparison of Labor and Delivery Care Provided by Certified Nurse-Midwives and Physicians: A Systematic Review, 1990 to 2008.” *Women’s Health Issues*, vol. 22, no. 1 (2012): e73–e81, doi: 10.1016/j.whi.2011.06.005.

² Rayburn, W.F. et al. “Distribution of American Congress of Obstetricians and Gynecologists Fellows and Junior Fellows in Practice in the United States.” *Obstet Gynecol*, vol. 119, no. 5 (2012): 1017, doi: 10.1097/AOG.0b013e31824cfe50.

³ Rayburn, William F., Stephen M. Petterson, and Robert L. Phillips. “Trends in Family Physicians Performing Deliveries, 2003–2010.” *Birth (Berkeley, Calif.)* 41.1 (2014): 26–32.

Physicians providing maternity care.⁴ Makaroff, et al. evaluated American Board of Family Medicine survey data collected from every family physician during application for the Maintenance of Certification Examination to determine the percentage of family physicians that provided maternity care from 2000 to 2010. This research team's findings are in line with the results of the research conducted by Rayburn, Petterson, and Phillips in that they also found that maternity care provision by family physicians declined from 23.3 percent in 2000 to 9.7 percent in 2010 ($p < 0.0001$). Furthermore, in 2018, a study from Goldstein, et al. shows that the percentage of family practitioners offering low and high volume maternity care services continues to decline in both the United States and Canada and is now at less than 5 and 1 percent, respectively. These findings are based on data from the American Board of Family Medicine Examination

questionnaires. The data specifically showed that the number of family practitioners who offered high volume obstetric services has declined by 50 percent since 2009.⁵

Thus, while family physicians continue to play an important role in providing maternity care in many parts of the United States, there is a documented decline in the percentage of family physicians providing maternity care. HRSA recognizes the important contribution all of these professionals play in the delivery of obstetric care. However, as there is also not currently detailed nationwide data readily available outlining the number of hours individual providers provide these services, HRSA did not have an analytical basis for how to include them consistently. HRSA will continue to review the availability of these data points to determine if additional provider types (particularly Family Medicine Physicians, but also including

General Surgeons, Anesthesiologists, Pediatricians, Doulas, Lactation Specialists, Physician Assistants, Advance Practice Registered Nurses, and Registered Nurses who provide Women's Health services) may be incorporated into the MCTA scoring criteria in the future. HRSA is especially interested in recommendations for how to determine the amount of time Family Medicine Physicians spend providing maternity care services, as they may be the only providers of maternity services in areas with no OB/GYNs or CNMs. HRSA welcomes comments on how to incorporate these providers into future iterations of MCTA scoring, and any detailed nationwide data that may be available to do so.

HRSA is seeking feedback on the assigned point values in the distribution, which are proposed to be as follows:

Population-to-provider ratio	Points
Ratio $\geq 6,000:1$, or No CNMs or OB-GYNs and Population (Pop) ≥ 500	5
6,000:1 >Ratio $\geq 5,000:1$, or No CNMs or OB-GYNs and Pop ≥ 400	4
5,000:1 >Ratio $\geq 3,000:1$, or No CNMs or OB-GYNs and Pop ≥ 300	3
3,000:1 >Ratio $\geq 2,000:1$, or No CNMs or OB-GYNs and Pop ≥ 200	2
2,000:1 >Ratio $\geq 1,500:1$, or No CNMs or OB-GYNs and Pop ≥ 100	1
Ratio $< 1,500:1$, or No CNMs or OB-GYNs and Pop < 100	0

Score for Percentage of Population With Income at or Below 200 Percent of the Federal Poverty Level

HRSA proposes to incorporate poverty data from the U.S. Census Bureau into the MCTA composite score, as the majority of commenters highlighted the disparities that women

living in poverty face in accessing necessary maternity health services. The percentage of people living in the service area at or below 200 percent of the FPL will be used to score MCTAs, based on recommendations from commenters and poverty data from the U.S. Census Bureau. Maternal health

literature demonstrates a high correlation between low income, low health status, and poor maternal health outcomes.⁶

HRSA is seeking feedback on the assigned point values in the distribution, which are proposed as follows:

Population with income at or below 200% FPL ratio	Points
Percentage of population with income at or below 200% FPL $\geq 55\%$	6
55% >Percentage of population with income at or below 200% FPL $\geq 50\%$	5
50% >Percentage of population with income at or below 200% FPL $\geq 45\%$	4
45% >Percentage of population with income at or below 200% FPL $\geq 40\%$	3
40% >Percentage of population with income at or below 200% FPL $\geq 35\%$	2
35% >Percentage of population with income at or below 200% FPL $\geq 30\%$	1
Percentage of population with income at or below 200% FPL $< 30\%$	0

Score for Travel Distance/Time to Nearest Source of Accessible Care Outside of the MCTA

Several of the commenters highlighted the barriers in travel time and transportation that many women face in accessing maternity care

services, particularly in rural and underserved areas. In keeping with this feedback, HRSA will incorporate the travel time and distance to the Nearest Source of Care into the MCTA composite score. The Nearest Source of Care is defined as the closest provider

location where the residents of the area or designated population have access to comprehensive maternity care services. Scientific literature presented by the American Academy of Pediatrics Committee on Fetus and Newborn and the American College of Obstetricians

⁴ Makaroff, Laura A. et al. "Factors Influencing Family Physicians' Contribution to the Child Health Care Workforce." *Annals of family medicine* 12.5 (2014): 427–431.

⁵ Goldstein, Jessica, et al., "Supporting Family Physician Maternity Care Providers" *Family Medicine* 50:9 (2018).

⁶ Aftab, et al. "Effects of Poverty on Pregnant Women." *Department of Gynaecology and Obstetrics, Dow University of Health Sciences, Lyari General*

Hospital, Karachi, vol. 51, no.1 (2012). March of Dimes, "Nowhere to Go: Maternity Care Deserts Across the US," (2018), available at https://www.marchofdimes.org/materials/Nowhere_to_Go_Final.pdf.

and Gynecologists Committee on Obstetric Practice established that an individual's proximity to care can affect health outcomes.⁷ Specifically for

maternity care, the literature indicates that decision-to-incision time for emergency cesarean delivery is 30 minutes.⁸

HRSA is seeking public comment on the assigned point values in the distribution, which are proposed as follows:

Travel time and distance	Points
Time ≥105 min, or Distance ≥105 miles	6
105 min >Time ≥90 min or 105 miles > Distance ≥90 miles	5
90 min >Time ≥75 min, or 90 miles > Distance ≥75 miles	4
75 min >Time ≥60 min, or 75 miles > Distance ≥60 miles	3
60 min >Time ≥45 min, or 60 miles > Distance ≥45 miles	2
45 min >Time ≥30 min, or 45 miles > Distance ≥30 miles	1
Time <30 min, and Distance <30 miles	0

Score for Fertility Rate

HRSA proposes to include fertility rate as a criteria for the MCTA score to reflect the increased need for maternity care services among populations which

experience a higher rate of births. Women of childbearing age will be derived from the American Community Survey and births will be derived from the National Vital Statistics System.

HRSA is seeking public comment on the assigned point values in the distribution, which are proposed as follows:

Fertility rate	Points
Fertility Rate ≥90th Percentile	2
90th Percentile >Fertility Rate ≥50th Percentile	1
Fertility Rate <50th Percentile	0

Score for Social Vulnerability Index

Several MCTA commenters highlighted associations between adverse maternal health outcomes and non-clinical factors such as poverty, unemployment, lack of adequate housing and transportation, minority status, and English language proficiency. The Agency for Toxic Substances and Disease Registry's Geospatial Research, Analysis and Services Program within the Centers for Disease Control and Prevention (CDC) created databases to help emergency response planners and public health officials identify and map communities that will most likely need support before, during, and after a hazardous event. Per the CDC, Social Vulnerability refers to the resilience of communities when confronted by external hazards such as natural or human-caused disasters, or disease outbreaks.

One such database is the Social Vulnerability Index (SVI), which uses

U.S. Census data to determine the social vulnerability of every census tract based on the following four themes:

Socioeconomic status, household composition and disability, minority status and language, and housing type and transportation. Each tract receives a separate percentile ranking which is represented by a number between zero and one for each of the four themes, as well as an overall ranking. These themes take into account various factors ranging from educational attainment and unemployment to multi-unit structures and single parent households.

Public health literature supports the correlation between low English proficiency and late initiation of prenatal care as well as adverse perinatal outcomes due to lack of communication between the provider and patient.^{9 10} Currently, literature is not available that evaluates the use of the entire SVI to specifically quantify maternal health outcomes. However,

many of the individual factors within the SVI are known social determinants of health. Social determinants of health are the conditions in the environment in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. These social determinants of health as represented within the SVI, are critical in understanding external factors that affect the need for maternity care services.

A score for overall social vulnerability will be incorporated into the MCTA composite score to reflect the increased need for maternity care services among populations which experience a higher rate of social vulnerability using the CDC's SVI. HRSA is seeking public comment on the assigned point values in the distribution, which are proposed as follows:

Social Vulnerability Index	Points
Social Vulnerability ≥75th Percentile	2
75th Percentile > Social Vulnerability ≥50th Percentile	1
Social Vulnerability <50th Percentile	0

⁷ Kilpatrick, Sarah J., et al. *Guidelines for Perinatal Care*. 8th ed., American Academy of Pediatrics, 2017.

⁸ Roa, Lina et al., "Travel Time to Access Obstetric and Neonatal Care in the United States." *Obstetrics and Gynecology* (New York. 1953) vol. 136, no. 3 (2020): 610–612.

⁹ Pope, Charlene. "Addressing Limited English Proficiency and Disparities for Hispanic Postpartum Women." *Journal of Obstetric, Gynecologic & Neonatal Nursing*, vol. 34, no. 4, 2005, pp. 512–20. *Crossref*, doi:10.1177/0884217505278295.

¹⁰ Vinson, Abigail, et al. "131: Maternal Language, Severe Maternal Morbidity and Access to Prenatal

Care." *American Journal of Obstetrics and Gynecology*, vol. 222, no. 1, 2020, pp. S99–100. *Crossref*, doi:10.1016/j.ajog.2019.11.147.

Score for Maternal Health Indicators

Many of the comments HRSA received raised concerns about social determinants of health that have an impact on women's health outcomes, not only during and after pregnancy, but also before and in between pregnancies. In order to address these concerns, HRSA is seeking public comment on the use of maternal health indicators as scoring criteria for MCTAs. MCTA scores will consider health indicators that are associated with poor maternal health outcomes by looking at various data points related to pre-pregnancy health status and when prenatal care began. Scores will consider pre-pregnancy obesity, diabetes, and hypertension, as well as whether prenatal care began in the first trimester, as these are all conditions which may require additional workforce capacity to adequately address community needs. Only women of childbearing age will be considered for these indicators. HRSA will use the National Vital Statistics

System as the data source to determine the sub-score for each of these four (4) maternal health indicators.

Public health literature demonstrates that higher rates of obesity, diabetes, or hypertension, and later onset of prenatal care are all associated with poorer maternal health outcomes and will help identify the need for additional health professionals. A 2018 Centers for Disease Control and Prevention report on preconception health surveillance identified priority indicators for adverse maternal health outcomes.¹¹ The study reviewed 50 preconception health indicators and prioritized those indicators that are most suitable for surveillance purposes. Weight, diabetes, and hypertension were all among the top 10 preconception health indicators recommended for surveillance.¹²

HRSA also considered incorporating maternal mortality data into the MCTA score. However, due to data suppression for privacy reasons, this data is not readily available publicly or to HRSA below the state level. As both HPSAs

and MCTAs are designed to be able to provide meaningful differentiation of need between communities at a local level, HRSA decided not to incorporate maternal mortality data at this time. If this data eventually becomes available to HRSA at the county level or below, HRSA may include it in future MCTA score calculation.

HRSA is seeking public comment on the proposed criteria and point scale distributions below. Service areas may receive one point each for meeting the criteria.

- *Pre-Pregnancy Obesity*

Pre-pregnancy obesity is defined as having a Body Mass Index of 30 or higher. One point will be awarded if the prevalence of pre-pregnancy obesity in the area is greater than or equal to the 75th percentile among all counties in the United States. If the prevalence of pre-pregnancy obesity in the area is less than the 75th percentile among all counties, zero points will be awarded.

Pre-pregnancy obesity	Points
Prevalence of pre-pregnancy obesity $\geq$ 75th percentile	1
Prevalence of pre-pregnancy obesity <75th percentile	0

- *Pre-Pregnancy Diabetes*

One point will be awarded if the prevalence of pre-pregnancy diabetes in

the area is greater than or equal to the 75th percentile among all counties in the United States. If the prevalence of

pre-pregnancy diabetes in the area is less than the 75th percentile among all counties, zero points will be awarded.

Pre-pregnancy diabetes	Points
Prevalence of pre-pregnancy diabetes $\geq$ 75th percentile	1
Prevalence of pre-pregnancy diabetes <75th percentile	0

- *Pre-Pregnancy Hypertension*

One point will be awarded if the prevalence of pre-pregnancy

hypertension among women in the area is greater than or equal to the 75th percentile among all counties in the nation. If the prevalence of pre-

pregnancy hypertension among women in the area is less than the 75th percentile among all counties, zero points will be awarded.

Pre-pregnancy hypertension	Points
Prevalence of pre-pregnancy hypertension $\geq$ 75th percentile	1
Prevalence of pre-pregnancy hypertension <75th percentile	0

- *Prenatal Care Initiation in the 1st Trimester*

One point will be awarded if the prevalence of women who did not

initiate prenatal care in the first trimester of their pregnancy is greater than or equal to the 75th percentile among all counties in the nation. Zero points will be awarded if the prevalence

of women who did not initiate prenatal care in the first trimester of their pregnancy is less than the 75th percentile among all counties.

Prenatal care in first trimester	Points
Prevalence of No Prenatal Care in First Trimester $\geq$ 75th percentile	1
Prevalence of No Prenatal Care in First Trimester <75th percentile	0

¹¹ Robbins, Cheryl L., et al. "Preconception Health Indicators for Public Health Surveillance."

Journal of Women's Health, vol. 27, no. 4 (2018): 430–43.

¹² *Ibid.*

Diana Espinosa,
Acting Administrator.

[FR Doc. 2021–20855 Filed 9–24–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statutory Requirements and Process Standardization: Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Model Eligibility Review

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for public comment.

SUMMARY: HRSA, in partnership with the Administration for Children and Families (ACF) within HHS, oversees the MIECHV Program, which supports voluntary, evidence-based home visiting services during pregnancy and to families with young children up to kindergarten entry. HRSA proposes to standardize a process for also assessing Home Visiting Evidence of Effectiveness (HomVEE)-approved home visiting models against the MIECHV statutory requirements for a model to determine which of the HomVEE-approved models can be used to implement the MIECHV Program.

DATES: Comments on this request for public comment should be received no later than November 26, 2021.

ADDRESSES: Submit your comments to homevisiting@hrsa.gov with “MIECHV Model Eligibility” in the subject line.

SUPPLEMENTARY INFORMATION:

Invitation to comment: HRSA invites comments regarding this notice. To ensure that your comments are clearly stated, please identify the section of this notice that your comments address.

1.0 Background

The MIECHV Program provides voluntary, evidence-based home visiting services to pregnant people and families with young children up to kindergarten entry living in at-risk communities.¹ States, jurisdictions, certain non-profit organizations, and Tribal entities are eligible to receive funding from the MIECHV Program to implement service delivery model(s) that meet statutory requirements, including HHS criteria for evidence of effectiveness.^{2,3}

The MIECHV authorizing statute specifies that a model selected by an eligible entity must include certain key components, including that it “conform to a clear consistent home visitation model that has been in existence for at least 3 years and is research-based, grounded in relevant empirically-based knowledge, linked to program determined outcomes, associated with a national organization or institution of higher education that has comprehensive home visitation program standards that ensure high-quality service delivery and continuous program quality improvement.”⁴ In addition, the MIECHV-funded program must adhere to statutory standards applicable to model use, including adherence “to a clear, consistent model that satisfies the requirements of being grounded in empirically-based knowledge related to home visiting and linked to the benchmark areas specified in [statute] and the participant outcomes

described in [statute] related to the purposes of the program.”⁵ Home visiting programs could not achieve the standards described in the program’s authorizing statute without the support of home visiting models.

HRSA, in collaboration with ACF, has developed a proposed transparent and standardized process for assessing home visiting service delivery model(s) against statutory requirements to determine model eligibility for implementation through the MIECHV Program. Through this notice, HRSA seeks to provide public notice of the proposed process and gather public comment, including from stakeholders. Since the establishment of this process may affect critical decision-making, and to better understand the implications of these changes for various stakeholders, HRSA seeks public comment on the proposed process for assessing home visiting models against the MIECHV statutory requirements. HRSA will consider these comments in finalizing this process.

2.0 Process for Assessing Eligibility Against Statutory Requirements for a Home Visiting Model

This notice presents statutory requirements for a MIECHV service delivery model and the proposed process to assess home visiting models against each MIECHV statutory requirement. Then, the notice will present the proposed process, with timeline, for collecting information to assess whether the model(s) meet these requirements and therefore can be used to implement the MIECHV Program.

2.1 Model Eligibility Requirements

Requirement	Standard used	Statutory citation of requirement
REQUIREMENT (1): Model is appropriate for voluntary service provision.	There is evidence of model effectiveness in a voluntary setting.	Social Security Act, Title V, § 511(e)(7)(A).
REQUIREMENT (2): The model conforms to a clear consistent home visitation model.	The model conforms to HomVEE’s definition of an early childhood home visiting model.	Social Security Act, Title V, § 511(d)(3)(A)(i)(I).
REQUIREMENT (3): The model . . . has been in existence for at least 3 years.	The model is currently active and was first developed at least 3 years ago; OR The model is inactive and was first developed at least 3 years before a model developer stopped providing implementation support; OR The model was implemented as a demonstration project that lasted at least 3 years.	Social Security Act, Title V, § 511(d)(3)(A)(i)(I).

¹ The MIECHV Program is authorized by Social Security Act, Title V, § 511; Section 50601 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) (BBA) extended appropriated funding for the MIECHV Program through FY 2022.

² In current practice, HHS uses the HomVEE review to conduct a thorough and transparent review of the home visiting research literature and provide an assessment of the evidence of effectiveness for home visiting program models that

target families with pregnant people and children from birth to kindergarten. Information about the HomVEE review is at <https://homvee.acf.hhs.gov/>.

³ By law, state and jurisdictional awardees must spend the majority of their MIECHV Program grants to implement evidence-based home visiting models, with up to 25 percent of funding available to implement a model that conforms to a promising and new approach to achieving the benchmark areas specified in Social Security Act, Title V, § 511

(d)(1)(A) and the participant outcomes described in Social Security Act, Title V, § 511 (d)(2)(B), has been developed or identified by a national organization or institution of higher education, and will be evaluated through well-designed and rigorous process.

⁴ Social Security Act, Title V, § 511(d)(3)(A)(i)

⁵ Social Security Act, Title V, § 511(d)(3)(B)

Requirement	Standard used	Statutory citation of requirement
REQUIREMENT (4): The model . . . is research-based [and] grounded in relevant empirically-based knowledge.	The model is evidence-based and grounded in relevant empirically-based knowledge, per the HHS HomVEE criteria for evidence of effectiveness.	Social Security Act, Title V, § 511(d)(3)(A)(i)(I).
REQUIREMENT (5): The model . . . has demonstrated significant . . . positive outcomes . . . when evaluated using well-designed and rigorous . . . research designs.	The model has demonstrated significant positive outcomes when evaluated, per the HHS HomVEE criteria for evidence of effectiveness.	Social Security Act, Title V, § 511(d)(3)(A)(i)(I).
REQUIREMENT (6): The model [is] associated with a national organization or institution of higher education (IHE) . . .	The model was developed by, is currently supported by, OR is currently being evaluated by, a national organization ⁶ or IHE ⁷ .	Social Security Act, Title V, § 511(d)(3)(A)(i)(I).
REQUIREMENT (7): The national organization or IHE with which the model is associated has comprehensive home visitation program standards that ensure high quality service delivery and continuous program quality improvement.	This requirement is met if Requirement 6 is met. AND (A) The organization or IHE can provide implementing agencies with documentation of its home visitation program standards associated with the model that ensure high quality service delivery (such as fidelity standards or implementation guidance);. AND (B) The model supports continuous program quality improvement (such as through the use of specific processes, systems, or tools).	Social Security Act, Title V, § 511(d)(3)(A)(i)(I).
REQUIREMENT (8): Employ well-trained and competent staff.	(A) The model requires that home visiting staff, including home visitors and home visiting supervisors, receive pre- AND in-service training. Staff must include, at a minimum, home visitors and home visiting supervisors. AND (B) The model establishes educational requirements and/or competencies around knowledge, skills, abilities, and experience to ensure that program staff are able to deliver the model.	Social Security Act, Title V, § 511(d)(3)(B)(ii).
REQUIREMENT (9): Maintain high quality supervision to establish home visitor competencies.	(A) The model has quality supervisory requirements to establish and maintain home visitor competencies, including the mode and frequency of supervision; AND (B) The model has a documented plan for supporting and assessing the quality of supervision.	Title V, § 511(d)(3)(B)(iii).
REQUIREMENT (10): Demonstrate strong organizational capacity to implement the activities involved.	The model has ongoing support to implement the model, including implementation tailored to the communities served.	Title V, § 511(d)(3)(B)(iv).
REQUIREMENT (11): Establish appropriate linkages and referral networks to other community resources and supports for eligible families.	The model has guidance OR a process to support local implementing agencies' ability to establish and document appropriate linkages and referrals to community resources and supports for eligible MIECHV program participants.	Title V, § 511(d)(3)(B)(v).
REQUIREMENT (12): Monitor the fidelity of program implementation to ensure that services are delivered pursuant to the specified model.	(A) The model has standards OR a system for monitoring fidelity of program implementation on an ongoing basis; AND (B) The model provides training OR training materials for supervisors and home visitors on fidelity standards.	Title V, § 511(d)(3)(B)(vi).

2.2 Information Collection and Timeline

HRSA, in collaboration with ACF, proposes to conduct model developer

⁶ A national organization may be in the United States (including tribal nations or within any of the U.S. territories) or non-U.S. based; an organization is "national" if it has an office that is able to

queries to gather information necessary for assessing models against the MIECHV Program statutory

support implementation in two or more states, tribes, territories, or regions, or similarly defined geographic areas outside of the United States.

⁷ An IHE may be an accredited community college, college, or university in the United States or another country.

requirements. Requirements related to HHS evidence of effectiveness (see Section 2.1; requirements 1, 2, 4, and 5; above) are currently collected and assessed through the HomVEE annual review process; HRSA has concluded that this process is sufficient to assess these requirements and is not proposing

any changes to the HomVEE evidence review through this notice.

Following the publication of this notice, the associated comment period, and publication of a final model eligibility review process, HRSA anticipates assessing all models that have been determined to meet the HHS criteria for evidence of effectiveness, as determined by HomVEE review, against the statutory requirements for model implementation through the MIECHV Program. HRSA intends to contact model developers and request they provide information about model characteristics, resources, and processes using a standard set of survey questions. HRSA will assess information and resources provided by models against the standards for each requirement, described above, to determine eligibility for implementation through the MIECHV Program. Following this initial review, all models determined to be eligible for implementation through the MIECHV Program will be reassessed against the statutory requirements for a model every 3 years.

As the HomVEE review determines that new models meet HHS criteria for evidence of effectiveness, HRSA intends to assess these models against the MIECHV statutory requirements. Any such model that does not meet statutory requirements for implementation through the MIECHV Program will be reassessed annually until the model either meets remaining statutory requirements or a model developer indicates that they no longer want the model to be assessed for implementation through the MIECHV program.

HRSA anticipates applying the updated process for assessing model eligibility against MIECHV statutory requirements beginning in Fiscal Year (FY) 2024. Specifically, the updated process will apply to all HomVEE-

approved models to determine eligibility for implementation through the MIECHV Program beginning in the FY 2024 MIECHV Notice of Funding Opportunity.

3.0 Request for Information

Through this notice, HRSA is soliciting information from a broad array of stakeholders on the proposed process for assessing home visiting models against the MIECHV statutory requirements for a model to determine eligibility for implementation through the MIECHV Program.

Responses to this notice will inform HRSA's ongoing discussion with the aim of publishing a final process for assessing home visiting models against statutory requirements. This notice is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of HRSA or HHS.

Diana Espinosa,

Acting Administrator.

[FR Doc. 2021-20853 Filed 9-24-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-4040-0006]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 26, 2021.

ADDRESSES: Submit your comments to sagal.musa@hhs.gov or by calling (202) 205-2634.

FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 4040-0006-New-60D and project title for reference, to Sagal Musa, email: sagal.musa@hhs.gov, or call (202) 205-2634 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Budget Information for Non-Construction Programs (SF-424A).

Type of Collection: Renewal.

OMB No.: 4040-0006.

Abstract: Budget Information for Non-Construction Programs (SF-424A) is used by applicants to apply for Federal financial assistance. The Budget Information for Non-Construction Programs (SF-424A) form allows the applicants to provide budget details as part of their grant proposals. This form is evaluated by Federal agencies as part of the overall grant application. This IC expires on February 28, 2022.

Grants.gov seeks a three-year clearance of these collections.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Budget Information for Non-Construction Programs (SF-424A).	Grant-seeking organizations.	12,775	1	1	12,775
Total			1		12,775

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2021-20835 Filed 9-24-21; 8:45 am]

BILLING CODE 4151-AE-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**[Document Identifier: OS-4040-0008]****Agency Information Collection Request; 60-Day Public Comment Request****AGENCY:** Office of the Secretary, HHS.**ACTION:** Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 26, 2021.

ADDRESSES: Submit your comments to sagal.musa@hhs.gov or by calling (202) 205-2634.

FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 4040-0008-New-60D and project title for reference, to Sagal Musa, email: sagal.musa@hhs.gov, or call (202) 205-2634 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity

of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Budget Information for Construction Programs (SF-424C).

Type of Collection: Renewal.

OMB No.: 4040-0008.

Abstract: Budget Information for Construction Programs (SF-424C) is used by applicants to apply for Federal financial assistance. The Budget Information for Construction Programs (SF-424C) form allows the applicants to provide budget details as part of their grant proposals. This form is evaluated by Federal agencies as part of the overall grant application. This IC expires on February 28, 2022. *Grants.gov* seeks a three-year clearance of these collections.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Budget Information for Construction Programs (SF-424C).	Grant-seeking organizations.	239	1	1	239
Total			1		239

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2021-20837 Filed 9-24-21; 8:45 am]

BILLING CODE 4151-AE-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**[Document Identifier: OS-4040-0003]****Agency Information Collection Request; 60-Day Public Comment Request****AGENCY:** Office of the Secretary, HHS.**ACTION:** Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 26, 2021.

ADDRESSES: Submit your comments to sagal.musa@hhs.gov or by calling (202) 205-2634.

FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 4040-0003-New-60D and project title for reference, to Sagal Musa, email: sagal.musa@hhs.gov, or call (202) 205-2634 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Application for Federal Domestic Assistance-Short Organizational.

Type of Collection: Renewal.

OMB No.: 4040-0003.

Abstract: Application for Federal Domestic Assistance-Short Organizational is used by applicants to apply for Federal financial assistance. The Application for Federal Domestic Assistance-Short Organizational allows the applicants to provide organizational details as part of their grant proposals. This form is evaluated by Federal agencies as part of the overall grant application. This IC expires on February 28, 2022. *Grants.gov* seeks a three-year clearance of these collections.

Type of Respondent: The Application for Federal Domestic Assistance-Short Organizational form is used by organizations to apply for Federal financial assistance in the form of grants. These forms are submitted to the Federal grant-making agencies for evaluation and review.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Application for Federal Domestic Assistance- Short Organizational.	Grant-seeking organiza- tions.	936	1	1	936
Total			1		936

Sherrette A. Funn,

*Paperwork Reduction Act Reports Clearance
Officer, Office of the Secretary.*

[FR Doc. 2021-20831 Filed 9-24-21; 8:45 am]

BILLING CODE 4151-AE-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-4040-0007]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 26, 2021.

ADDRESSES: Submit your comments to sagal.musa@hhs.gov or by calling (202) 205-2634.

FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 4040-0007-New-60D and project title for reference, to Sagal Musa, email: sagal.musa@hhs.gov, or call (202) 205-2634 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to

enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Assurances for Non-Construction Programs (SF424B).

Type of Collection: Renewal.

OMB No. 4040-0007.

Abstract

Assurances for Non-Construction Programs (SF-424B) is used by applicants to apply for Federal financial assistance. The Assurances for Non-Construction Programs (SF-424B) form requests that the applicants certify specified required assurances as part of their grant proposals. This form is evaluated by Federal agencies as part of the overall grant application. This IC expires on February 28, 2022.

Grants.gov seeks a three-year clearance of these collections.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Assurances for Non-Construction Programs (SF-424B).	Grant-seeking organizations	9,772	1	0.5	4,886
Total			1		4,886

Sherrette A. Funn,

*Paperwork Reduction Act Reports Clearance
Officer, Office of the Secretary.*

[FR Doc. 2021-20838 Filed 9-24-21; 8:45 am]

BILLING CODE 4151-AE-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; SARS-CoV-2, COVID-19 and Consequences of Alcohol Use (RFA AA 21-002, AA 21-003 and AA21-004).

Date: November 5, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700 B Rockledge Drive, Room 2114, Bethesda, MD 20892, (301) 451-2067, srinivar@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research

and Research Support Awards., National Institutes of Health, HHS)

Dated: September 22, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-20885 Filed 9-24-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The 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 Center for Complementary and Integrative Health Special Emphasis Panel; Neural Mechanisms of Force-Based Manipulations: High Priority Research Networks.

Date: October 29, 2021.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Complementary and Integrative Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sonia Elena Nanescu, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH/NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892-5475, sonia.nanescu@nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: September 22, 2021.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-20879 Filed 9-24-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development of a Bispecific T Cell Engager for the Treatment and Cure of HIV-1

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Gilead Sciences, Inc. ("Gilead") located in Foster City, CA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before October 12, 2021 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Rose M. Freel, Ph.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 8490 Progress Drive, Suite 400, Frederick, MD 21701 (for business mail), Telephone: (301)624-8775; Email: rose.freel@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. 61/347,088, filed May 21, 2010 and entitled "High-affinity fully functional soluble single-domain human CD4, antibodies, and related fusion proteins" [HHS Reference No. E-103-2010/0-US-01];

PCT Patent Application PCT/US2011/037439, filed May 20, 2011 and entitled "High-affinity fully functional soluble single-domain human CD4, antibodies, and related fusion proteins" [HHS Reference No. E-103-2010/0-PCT-02];

United States Patent No. 8,911,728, granted December 16, 2014, corresponding to U.S. Application No. 13/699,535, filed January 11, 2013, entitled "High-affinity fully functional soluble single-domain human CD4, antibodies, and related fusion proteins" [HHS Reference No. E-103-2010-1-US-03]; and

European Patent Application No. 21185510.1, filed July 14, 2021, entitled

"High-affinity fully functional soluble single-domain human CD4, antibodies, and related fusion proteins" [HHS Reference No. E-103-2010-1-EP-04].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights for the following: "For use in an HIV Bispecific T cell engager construct comprising the CD4 mD1 which will be utilized in therapeutic regimens to treat and cure people living with HIV."

This technology discloses highly soluble and stable single-domain sCD4 proteins that have therapeutic potential for inhibition of HIV-1 viral entry into cells. CD4 is a glycoprotein present on the surface of mature CD4+ T cells and is the primary receptor allowing the entry of HIV-1 into cells. The interaction between the CD4 protein on the cell surface and the viral envelope glycoprotein is key for infecting a cell. As a result, the single-domain sCD4 proteins described in this invention have potential uses in a variety of therapeutic strategies attempting to prevent the interaction between cellular CD4 and the viral envelope and therefore, inhibition of viral entry.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 21, 2021.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2021-20908 Filed 9-24-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The 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 Nursing Research Initial Review Group.

Date: October 21–22, 2021.

Time: 9:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Nursing Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Cheryl Nordstrom, Ph.D., Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Suite 703H, Bethesda, MD 20892, (301) 827-1499, cheryl.nordstrom@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: September 22, 2021.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-20884 Filed 9-24-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Muscle and Exercise Physiology Study Section.

Date: October 19–20, 2021.

Time: 9:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, (301) 496-8551, ingrahamrh@mail.nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Molecular Genetics B Study Section.

Date: October 25–26, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michael L. Bloom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7804, Bethesda, MD 20892, 301-451-0132, bloomm2@mail.nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Arthritis, Connective Tissue and Skin Study Section.

Date: October 26–27, 2021.

Time: 9:30 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Robert Gersch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, (301) 867-5309, robert.gersch@nih.gov.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Imaging Technology Development Study Section.

Date: October 28–29, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bernard Joseph Dardzinski, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827-3082, bernard.dardzinski@nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Healthcare and Health Disparities Study Section.

Date: October 28–29, 2021.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jessica Bellinger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, Bethesda, MD 20892, 301-827-4446, bellingerjd@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Cancer, Heart, and Sleep Epidemiology: A Study Section.

Date: October 28–29, 2021.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Denise Wiesch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7770, Bethesda, MD 20892, (301) 437-3478, wieschd@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 21, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-20881 Filed 9-24-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Quarterly IRS Interest Rates Used in Calculating Interest on Overdue Accounts and Refunds on Customs Duties

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

ACTION: General notice.

SUMMARY: This notice advises the public that the quarterly Internal Revenue Service interest rates used to calculate interest on overdue accounts

(underpayments) and refunds (overpayments) of customs duties will remain the same from the previous quarter. For the calendar quarter beginning October 1, 2021, the interest rates for overpayments will be 2 percent for corporations and 3 percent for non-corporations, and the interest rate for underpayments will be 3 percent for both corporations and non-corporations. This notice is published for the convenience of the importing public and U.S. Customs and Border Protection personnel.

DATES: The rates announced in this notice are applicable as of October 1, 2021.

FOR FURTHER INFORMATION CONTACT:

Bruce Ingalls, Revenue Division, Collection Refunds & Analysis Branch, 6650 Telecom Drive, Suite #100, Indianapolis, Indiana 46278; telephone (317) 298-1107.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to 19 U.S.C. 1505 and Treasury Decision 85-93, published in the **Federal Register** on May 29, 1985 (50 FR 21832), the interest rate paid on applicable overpayments or underpayments of customs duties must be in accordance with the Internal Revenue Code rate established under 26 U.S.C. 6621 and 6622. Section 6621 provides different interest rates applicable to overpayments: One for corporations and one for non-corporations.

The interest rates are based on the Federal short-term rate and determined by the Internal Revenue Service (IRS) on behalf of the Secretary of the Treasury on a quarterly basis. The rates effective for a quarter are determined during the first-month period of the previous quarter.

In Revenue Ruling 2021-17, the IRS determined the rates of interest for the calendar quarter beginning October 1, 2021, and ending on December 31, 2021. The interest rate paid to the Treasury for underpayments will be the Federal

short-term rate (0%) plus three percentage points (3%) for a total of three percent (3%) for both corporations and non-corporations. For corporate overpayments, the rate is the Federal short-term rate (0%) plus two percentage points (2%) for a total of two percent (2%). For overpayments made by non-corporations, the rate is the Federal short-term rate (0%) plus three percentage points (3%) for a total of three percent (3%). These interest rates used to calculate interest on overdue accounts (underpayments) and refunds (overpayments) of customs duties remain the same from the previous quarter. These interest rates are subject to change for the calendar quarter beginning January 1, 2022, and ending on March 31, 2022.

For the convenience of the importing public and U.S. Customs and Border Protection personnel, the following list of IRS interest rates used, covering the period from July of 1974 to date, to calculate interest on overdue accounts and refunds of customs duties, is published in summary format.

Beginning date	Ending date	Under-payments (percent)	Over-payments (percent)	Corporate Overpayments (Eff. 1-1-99) (percent)
070174	063075	6	6	
070175	013176	9	9	
020176	013178	7	7	
020178	013180	6	6	
020180	013182	12	12	
020182	123182	20	20	
010183	063083	16	16	
070183	123184	11	11	
010185	063085	13	13	
070185	123185	11	11	
010186	063086	10	10	
070186	123186	9	9	
010187	093087	9	8	
100187	123187	10	9	
010188	033188	11	10	
040188	093088	10	9	
100188	033189	11	10	
040189	093089	12	11	
100189	033191	11	10	
040191	123191	10	9	
010192	033192	9	8	
040192	093092	8	7	
100192	063094	7	6	
070194	093094	8	7	
100194	033195	9	8	
040195	063095	10	9	
070195	033196	9	8	
040196	063096	8	7	
070196	033198	9	8	
040198	123198	8	7	
010199	033199	7	7	6
040199	033100	8	8	7
040100	033101	9	9	8
040101	063001	8	8	7
070101	123101	7	7	6
010102	123102	6	6	5
010103	093003	5	5	4
100103	033104	4	4	3
040104	063004	5	5	4

Beginning date	Ending date	Under-payments (percent)	Over-payments (percent)	Corporate Overpayments (Eff. 1–1–99) (percent)
070104	093004	4	4	3
100104	033105	5	5	4
040105	093005	6	6	5
100105	063006	7	7	6
070106	123107	8	8	7
010108	033108	7	7	6
040108	063008	6	6	5
070108	093008	5	5	4
100108	123108	6	6	5
010109	033109	5	5	4
040109	123110	4	4	3
010111	033111	3	3	2
040111	093011	4	4	3
100111	033116	3	3	2
040116	033118	4	4	3
040118	123118	5	5	4
010119	063019	6	6	5
070119	063020	5	5	4
070120	123121	3	3	2

Dated: September 22, 2021.

Jeffrey Caine,

Chief Financial Officer, U.S. Customs and Border Protection.

[FR Doc. 2021–20917 Filed 9–24–21; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–LE–2021–0109; FF09L00000/FX/LE1811090000/201; OMB Control Number 1018–0092]

Agency Information Collection Activities; Federal Fish and Wildlife Applications and Reports—Law Enforcement

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before November 26, 2021.

ADDRESSES: Send your comments on the information collection request (ICR) by one of the following methods:

- *Internet (preferred):* <http://www.regulations.gov>. Follow the instructions for submitting comments on Docket No. FWS–HQ–LE–2021–0109.

- *Email:* Info_Coll@fws.gov.
- *U.S. mail:* Service Information Collection Clearance Officer, U.S. Fish

and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803.

Please reference Office of Management and Budget (OMB) Control Number 1018–0092 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at Info_Coll@fws.gov, or by telephone at (703) 358–2503. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA, 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies 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 especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this 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) How might the agency 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 response.

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 Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*) makes it unlawful to import or export wildlife or wildlife products for commercial purposes without first obtaining an import/export license (see 16 U.S.C. 1538(d)). The ESA also requires that fish

or wildlife be imported into or exported from the United States only at a designated port, or at a nondesignated port under certain limited circumstances (see 16 U.S.C. 1538(f)). This information collection includes the following permit/license application forms:

FWS Form 3–200–2, “Designated Port Exception Permit”

Under 50 CFR 14.11, it is unlawful to import or export wildlife or wildlife products at ports other than those designated in 50 CFR 14.12, unless you qualify for an exception. The following exceptions allow qualified individuals, businesses, or scientific organizations to import or export wildlife or wildlife products at a nondesignated port:

- (a) To export the wildlife or wildlife products for scientific purposes;
- (b) To minimize deterioration or loss;

or

- (c) To relieve economic hardship.

To request authorization to import or export wildlife or wildlife products at nondesignated ports, applicants must complete FWS Form 3–200–2.

Designated port exception permits can be valid for up to 2 years. We may require a permittee to file a report on activities conducted under authority of the permit.

FWS Form 3–200–3a, “Federal Fish and Wildlife Permit Application Form: Import/Export License—U.S. Entities,” and 3–200–3b, “Federal Fish and Wildlife Permit Application Form: Import/Export License—Foreign Entities”

It is unlawful to import or export wildlife or wildlife products for commercial purposes without first obtaining an import/export license (50 CFR 14.91). Applicants located in the United States must complete FWS Form 3–200–3a to request this license. Foreign applicants that reside or are located outside the United States must complete FWS Form 3–200–3b to request this license.

We use the information collected on FWS Forms 3–200–3a and 3–200–3b as an enforcement tool and management aid to (a) monitor the international wildlife market and (b) detect trends and changes in the commercial trade of wildlife and wildlife products. Import/export licenses are valid for up to 1 year. We may require a licensee to file a report on activities conducted under authority of the import/export license.

Proposed Revisions

Automation in eLicense System

With this submission, we also seek OMB approval to automate FWS Forms 3–200–2, “Designated Port Exception Permit” (50 CFR parts 13 and 14), Form 3–200–3a, “Federal Fish and Wildlife Permit Application Form: Import/Export License—U.S. Entities” (50 CFR parts 13 and 14), and Form 3–200–3b, “Federal Fish and Wildlife Permit Application Form: Import/Export License—Foreign Entities” (50 CFR parts 13 and 14) in a new eLicense system. This automation is expected to reduce the burden on the public. The eLicense system will also simplify the application process and give the applicant the ability to pay online through *Pay.gov* via credit card or direct bank payment. This will reduce the number of applicants requesting multiple licenses for the same business and will reduce the number of bad addresses and bounced checks that we receive.

Automation in ePermits System

With this submission, we propose a revision to the collection to obtain OMB approval to automate Form 3–200–44, “Permit Application Form: Registration of an Agent/Tannery under the Marine Mammal Protection Act (MMPA),” and Form 3–200–44a, “Registered Agent/Tannery Bi-Annual Inventory Report” in the Service’s “ePermits” system. The ePermits system is an automated permit application system that streamlines the permitting process to reduce public burden. Public burden reduction is a priority for the Service; the Assistant

Secretary for Fish, Wildlife, and Parks; and senior leadership at the Department of the Interior. The ePermits system fully automates the permitting process to improve the customer experience and to reduce time burden on respondents. This system also enhances the user experience by allowing users to enter data from any device that has internet access, including PCs, tablets, and smartphones. Furthermore, the system links the permit applicant to the *Pay.gov* system for payment of any associated permit application fees.

Until we have actual usage data from the eLicense and ePermits systems, we are splitting the previously approved public burden equally between hard copy and electronic submissions (see burden table below). After the forms are operational in the two systems for at least 12 18 months, the Service will have more reliable burden data to submit to OMB in conjunction with the next renewal of this collection.

Title of Collection: Federal Fish and Wildlife Applications and Reports—Law Enforcement; 50 CFR parts 13 and 14.

OMB Control Number: 1018–0092.

Form Number: FWS Forms 3–200–2, 3–200–3, 3–200–3a, 3–200–44, and 3–200–44a.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Individuals, private sector, and State/local/Tribal entities.

Respondent’s Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion for Forms 3–200–2, 3–200–3, 3–200–3a, 3–200–44 and reporting requirements and bi-annually for Form 3–200–44a.

Total Estimated Annual Nonhour Burden Cost: \$1,188,100. There is a \$100 fee associated with applications (Forms 3–200–2 and 3–200–3) received from individuals and the private sector. There is no fee for applications from government agencies or for processing reports.

Activity/requirement	Estimated number of annual respondents	Estimated number of annual responses	Total estimated annual responses	Completion time per response (hours)	Estimated total annual burden hours *
FWS Form 3–200–2, “Designated Port Exception Permit” (50 CFR parts 13 and 14) (Hardcopy)					
Individuals	289	1	289	1.25	361
Private Sector	361	1	361	1.25	451
Government	7	1	7	1.25	9
FWS Form 3–200–2, “Designated Port Exception Permit” (50 CFR parts 13 and 14) (eLicense)					
Individuals	289	1	289	1	289
Private Sector	361	1	361	1	361

Activity/requirement	Estimated number of annual respondents	Estimated number of annual responses	Total estimated annual responses	Completion time per response (hours)	Estimated total annual burden hours *
Government	7	1	7	1	7
FWS Form 3–200–3a, “Federal Fish and Wildlife Permit Application Form: Import/Export License—U.S. Entities” (50 CFR parts 13 and 14) (Hardcopy)					
Private Sector	5,099	1	5,099	1.25	6,374
FWS Form 3–200–3a, “Federal Fish and Wildlife Permit Application Form: Import/Export License—U.S. Entities” (50 CFR parts 13 and 14) (eLicense)					
Private Sector	5,099	1	5,099	1	5,099
FWS Form 3–200–3b, “Federal Fish and Wildlife Permit Application Form: Import/Export License—Foreign Entities” (50 CFR parts 13 and 14) (Hardcopy)					
Private Sector	190	1	190	1.25	238
FWS Form 3–200–3b, “Federal Fish and Wildlife Permit Application Form: Import/Export License—Foreign Entities” (50 CFR parts 13 and 14) (eLicense)					
Private Sector	190	1	190	1	190
Designated Port Exception Permit Report (50 CFR parts 13 and 14)					
Private Sector	5	1	5	1	5
Import/Export License Report (50 CFR parts 13 and 14)					
Private Sector	10	1	10	1	10
FWS Forms 3–200–44, “Permit Application Form: Registration of an Agent/Tannery under the Marine Mammal Protection Act (MMPA)” (Hardcopy)					
Private Sector	3	1	3	.3	1
FWS Forms 3–200–44, “Permit Application Form: Registration of an Agent/Tannery under the Marine Mammal Protection Act (MMPA)” (ePermits)					
Private Sector	3	1	3	.25	1
FWS Form 3–200–44a, “Registered Agent/Tannery Bi-Annual Inventory Report” (Hardcopy)					
Private Sector	10	2	20	1	20
FWS Form 3–200–44a, “Registered Agent/Tannery Bi-Annual Inventory Report” (ePermits)					
Private Sector	10	2	20	.75	15
Total:	11,933		11,953		13,430

* Rounded.

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.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2021–20937 Filed 9–24–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX21EE000101100]

Public Meeting of the National Geospatial Advisory Committee

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the U.S. Geological Survey (USGS) is publishing this notice to announce that a Federal Advisory Committee meeting of the National

Geospatial Advisory Committee (NGAC) will take place.

DATES: The meeting will be held as a webinar on Tuesday, October 12, 2021 from 1:00 p.m. to 5:00 p.m., and on Wednesday, October 13, 2021 from 1:00 p.m. to 5:00 p.m. (Eastern Daylight Time).

ADDRESSES: The meeting will be held on-line and via teleconference. Instructions for accessing the meeting will be posted at www.fgdc.gov/ngac. Comments can be sent to Ms. Dionne Duncan-Hughes, Group Federal Officer by email to gs-faca-mail@usgs.gov.

FOR FURTHER INFORMATION CONTACT: Mr. John Mahoney, Federal Geographic Data

Committee (FGDC), USGS, 909 First Avenue, Suite 800, Seattle, WA 98104; by email at jmahoney@usgs.gov; or by telephone at (206) 220-4621.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix 2), the Government in the Sunshine Act of 1976 (5 U.S.C. 552B, as amended), and 41 CFR 102-3.140 and 102-3.150.

Purpose of the Meeting: The NGAC provides advice and recommendations related to management of Federal and national geospatial programs, the development of the National Spatial Data Infrastructure (NSDI), and the implementation of the Geospatial Data Act of 2018 (GDA) and Office of Management and Budget Circular A-16. The NGAC reviews and comments on geospatial policy and management issues and provides a forum to convey views representative of non-federal stakeholders in the geospatial community. The NGAC meeting is one of the primary ways that the FGDC collaborates with its broad network of partners. Additional information about the NGAC meeting is available at: www.fgdc.gov/ngac.

Agenda Topics

- FGDC Update
- GDA Implementation
- Executive Order 14008/Climate Mapping Initiative
- Landsat Advisory Group
- Public-Private Partnerships
- Stakeholder Engagement
- Public Comment

Meeting Accessibility/Special Accommodations: The webinar meeting is open to the public and will take place from 1:00 p.m. to 5:00 p.m. on October 12 and from 1:00 p.m. to 5:00 p.m. on October 13. Members of the public wishing to attend the meeting should visit www.fgdc.gov/ngac or contact Mr. John Mahoney (see **FOR FURTHER INFORMATION CONTACT**). Webinar/conference line instructions will be provided to registered attendees prior to the meeting. Individuals requiring special accommodations to access the public meeting should contact Mr. John Mahoney (see **FOR FURTHER INFORMATION CONTACT**) at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Public Disclosure of Comments: There will be an opportunity for public comment during both days of the meeting. Depending on the number of people who wish to speak and the time available, the time for individual comments may be limited. Written

comments may also be sent to the Committee for consideration. To allow for full consideration of information by the Committee members, written comments must be provided to John Mahoney (see **FOR FURTHER INFORMATION CONTACT**) at least three (3) business days prior to the meeting. Any written comments received will be provided to the committee members before the meeting.

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 may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 5 U.S.C. Appendix 2)

Kenneth Shaffer,

Deputy Executive Director, Federal Geographic Data Committee.

[FR Doc. 2021-20905 Filed 9-24-21; 8:45 am]

BILLING CODE 4338-11-P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[212A2100DD/AAKC001030/
A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Agreement To Amend Secretarial Procedures

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice announces the approval of the Agreement Between the Mashantucket Pequot Tribe of Indians of Connecticut (Tribe) and the State of Connecticut (State) to amend the Tribe's Secretarial Procedures and Memorandum of Understanding (Amendment).

DATES: The Amendment took effect on September 10, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, paula.hart@bia.gov, (202) 219-4066.

SUPPLEMENTARY INFORMATION: Under the Indian Gaming Regulatory Act (IGRA), Public Law 100-497, 25 U.S.C. 2701 *et seq.*, upon the occurrence of certain circumstances the Secretary of the Interior (Secretary) shall issue

procedures providing for the operation of Class III gaming by an Indian Tribe. Those procedures are effective once issued. On May 31, 1991, the Secretary published a Notice of Final Mashantucket Gaming Procedures (Procedures) in the **Federal Register**. See 56 FR 24996. On July 27, 2021, the Mashantucket Pequot Tribe (Tribe) submitted proposed amendments to the Tribe's Procedures (Amendment) and Memorandum of Understanding with the State of Connecticut (MOU). On September 10, 2021, the Assistant Secretary—Indian Affairs approved the Amendment and MOU.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2021-20933 Filed 9-24-21; 8:45 am]

BILLING CODE 4337-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAK940000.L14100000.
BX0000.21X.LXSS001L0100]

Filing of Plats of Survey: Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of lands described in this notice are scheduled to be officially filed in the Bureau of Land Management (BLM), Alaska State Office, Anchorage, Alaska. The surveys, which were executed at the request of the Bureau of Indian Affairs and the BLM, are necessary for the management of these lands.

DATES: The BLM must receive protests by October 27, 2021.

ADDRESSES: You may buy a copy of the plats from the BLM Alaska Public Information Center, 222 W 7th Avenue, Mailstop 13, Anchorage, AK 99513. Please use this address when filing written protests. You may also view the plats at the BLM Alaska Public Information Center, Fitzgerald Federal Building, 222 W 7th Avenue, Anchorage, Alaska, at no cost.

FOR FURTHER INFORMATION CONTACT: Thomas B. O'Toole, Chief, Branch of Cadastral Survey, Alaska State Office, Bureau of Land Management, 222 W 7th Avenue, Anchorage, AK 99513; (907) 271-4231; totoole@blm.gov. People who use a telecommunications device for the deaf may call the Federal Relay Service (FRS) at 1-800-877-8339 to contact the BLM during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will

receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The lands surveyed are:

Copper River Meridian, Alaska

U.S. Survey No. 14533, accepted August 10, 2021, situated in T. 20 S., R. 19 E.

U.S. Survey No. 14547, accepted August 10, 2021, situated in T. 19 S., R. 17 E.

Seward Meridian, Alaska

T. 2 N., R. 19 W., accepted April 16, 2021.

U.S. Survey No. 4547, accepted May 28, 2021, situated in T. 12 N., R. 11 W.

U.S. Survey No. 8627, accepted August 22, 2021, situated in T. 7 S., R. 39 W.

A person or party who wishes to protest one or more plats of survey identified above must file a written notice of protest with the State Director for the BLM in Alaska. The protest may be filed by mailing to BLM State Director, Alaska State Office, Bureau of Land Management, 222 W 7th Avenue, Anchorage, AK 99513 or by delivering it in person to the BLM Alaska Public Information Center, Fitzgerald Federal Building, 222 W 7th Avenue, Anchorage, Alaska. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. You must file the notice of protest before the scheduled date of official filing for the plat(s) of survey being protested. The BLM will not consider any notice of protest filed after the scheduled date of official filing. A notice of protest is considered filed on the date it is received by the State Director for the BLM in Alaska during regular business hours; if received after regular business hours, a notice of protest will be considered filed the next business day. A written statement of reasons in support of a protest, if not filed with the notice of protest, must be filed with the State Director for the BLM in Alaska within 30 calendar days after the notice of protest is filed.

If a notice of protest against a plat of survey is received prior to the scheduled date of official filing, the official filing of the plat of survey identified in the notice of protest will be stayed pending consideration of the protest. A plat of survey will not be officially filed until the dismissal or resolution of all protests of the plat.

Before including your address, phone number, email address, or other personally identifiable information in a notice of protest or statement of reasons, you should be aware that the documents you submit, including your personally identifiable information, may be made publicly available in their entirety at any time. While you can ask the BLM to withhold your personally identifiable information from public review, we

cannot guarantee that we will be able to do so.

(Authority: 43 U.S.C. Chap. 3.)

Thomas O'Toole,

Chief Cadastral Surveyor, Alaska.

[FR Doc. 2021-20807 Filed 9-24-21; 8:45 am]

BILLING CODE 4310-JA-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0032675; PPWOCRADN0-PCU00RP14.R50000]

**Notice of Inventory Completion:
American Museum of Natural History,
New York, NY; Correction**

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The American Museum of Natural History (AMNH) has corrected an inventory of human remains and associated funerary objects, published in a Notice of Inventory Completion in the **Federal Register** on January 16, 2014. This notice corrects the number of associated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the American Museum of Natural History. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the American Museum of Natural History at the address in this notice by October 27, 2021.

FOR FURTHER INFORMATION CONTACT: Nell Murphy, American Museum of Natural History, Central Park West at 79th Street, New York, NY 10024, telephone (212) 769-5837, email nmurphy@amnh.org.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the correction of an inventory of human remains and associated

funerary objects under the control of the American Museum of Natural History, New York, NY. The human remains and associated funerary objects were removed from the Sebonac site in Shinnecock Hills, Suffolk County, NY.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

This notice corrects the number of associated funerary objects published in a Notice of Inventory Completion in the **Federal Register** (79 FR 2876-2877, January 16, 2014). The Museum recently received archival documentation housed in a different institution that pertains to the AMNH's excavations at Shinnecock Hills. This new information has led Museum staff to identify additional associated funerary objects. Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (79 FR 2877, January 16, 2014), column 1, paragraph 2, sentence 3 is corrected by substituting the following sentence:

The 145 associated funerary objects are 109 ceramic sherds; two fragmentary turtle shell cups; one fragmentary turtle shell; one lot of burnt earth; one gun flint; one draw shave scraper; one lot of oyster shells; one grinding stone; one fragmentary steatite dish; one fragment of a soapstone object; one net sinker; one broken bone awl; two clay concretions (one of which is ornamented with lines); one clay disk; two lots of marine shells; one animal jaw; one serrated quartz scrapper or saw; one lot of animal bones (including deer antler, deer, bird, fish and turtle bone); one lot of animal bone (including deer antler, a tooth and split deer bones); one lot of animal bone including a sturgeon scale and piece of turtle shell; one lot of charred fish bones; one lot of marine shells and animal tooth; seven quartz tools; one lot of lithic debitage and clay dog; And four lots of lithic debitage.

In the **Federal Register** (79 FR 2877, January 16, 2014), column 2, paragraph 1, bullet point 2 is corrected by substituting the following sentence:

Pursuant to 25 U.S.C. 3001(3)(A), the 145 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian

organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Nell Murphy, American Museum of Natural History, Central Park West at 79th Street, New York, NY 10024, telephone (212) 769-5837, email nmurphy@amnh.org, by October 27, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Shinnecock Indian Nation may proceed.

The American Museum of Natural History is responsible for notifying the Cayuga Nation; Delaware Tribe of Indians; Mashantucket Pequot Indian Tribe [previously listed as Mashantucket Pequot Tribe of Connecticut]; Mohegan Tribe of Indians of Connecticut [previously listed as Mohegan Indian Tribe of Connecticut]; Narragansett Indian Tribe; Oneida Indian Nation [previously listed as Oneida Nation of New York]; Oneida Nation [previously listed as Oneida Tribe of Indians of Wisconsin]; Onondaga Nation; Saint Regis Mohawk Tribe [previously listed as St. Regis Band of Mohawk Indians of New York]; Seneca Nation of Indians [previously listed as Seneca Nation of New York]; Seneca-Cayuga Nation [previously listed as Seneca-Cayuga Tribe of Oklahoma]; Shinnecock Indian Nation; Stockbridge Muncie Community, Wisconsin; Tuscarora Nation; and the Wampanoag Tribe of Gay Head (Aquinnah) that this notice has been published.

Dated: September 21, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021-20915 Filed 9-24-21; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0032654;
PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: Department of Anthropology, University of South Florida, Tampa, FL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of Anthropology, University of South Florida has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains

and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Department of Anthropology, University of South Florida. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Department of Anthropology, University of South Florida at the address in this notice by October 27, 2021.

FOR FURTHER INFORMATION CONTACT: Thomas J. Pluckhahn, Department of Anthropology, University of South Florida, 4202 E Fowler Avenue, SOC 107, Tampa, FL 33620-8100, telephone (813) 549-9742, email tpluckhahn@usf.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Department of Anthropology, University of South Florida, Tampa, FL. The human remains were removed from San Bernardino County, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Department of Anthropology, University of South Florida professional staff in consultation with representatives of the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California; Morongo Band of Mission Indians, California [previously listed as Morongo Band of Cahuilla Mission Indians of the Morongo Reservation]; and the San Manuel Band of Mission Indians, California [previously listed as

San Manuel Band of Serrano Mission Indians of the San Manuel Reservation].

The Augustine Band of Cahuilla Indians, California [previously listed as Augustine Band of Cahuilla Mission Indians of the Augustine Reservation]; Cabazon Band of Mission Indians, California; Cahuilla Band of Indians [previously listed as Cahuilla Band of Mission Indians of the Cahuilla Reservation, California]; Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California; Capitan Grande Band of Diegueno Mission Indians of California (Barona Group of Capitan Grande Band of Mission Indians of the Barona Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California); Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California; Ewiiapaayp Band of Kumeyaay Indians, California; Fort McDowell Yavapai Nation, Arizona; Iipay Nation of Santa Ysabel, California [previously listed as Santa Ysabel Band of Diegueno Mission Indians of the Santa Ysabel Reservation]; Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California; Jamul Indian Village of California; La Jolla Band of Luiseno Indians, California [previously listed as La Jolla Band of Luiseno Mission Indians of the La Jolla Reservation]; La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California; Los Coyotes Band of Cahuilla and Cupeno Indians, California [previously listed as Los Coyotes Band of Cahuilla & Cupeno Indians of the Los Coyotes Reservation]; Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California; Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California; Pala Band of Mission Indians [previously listed as Pala Band of Luiseno Mission Indians of the Pala Reservation, California]; Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation, California; Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, California; Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona; Ramona Band of Cahuilla, California [previously listed as Ramona Band or Village of Cahuilla Mission Indians of California]; Rincon Band of Luiseno Mission Indians of Rincon Reservation, California; San Pasqual Band of Diegueno Mission Indians of California; Santa Rosa Band of Cahuilla Indians, California [previously listed as Santa Rosa Band of Cahuilla Mission Indians of the Santa Rosa Reservation]; Soboba

Band of Luiseno Indians, California; Sycuan Band of the Kumeyaay Nation; Torres Martinez Desert Cahuilla Indians, California [previously listed as Torres-Martinez Band of Cahuilla Mission Indians of California]; and the Twenty-Nine Palms Band of Mission Indians of California were invited to consult but did not participate. Hereafter, all the above listed Indian Tribes are referred to as "The Consulted and Invited Tribes."

History and Description of the Remains

At an unknown date, human remains representing, at minimum, one individual were removed from an unknown site most likely located in San Bernardino County, CA. The human remains were acquired by the University of South Florida by way of a donation from the St. Petersburg (Florida) Museum of History, but neither institution has a record of when the human remains were transferred. Records indicate that the human remains were donated to the St. Petersburg Museum of History by Cyrus Belden on January 15, 1966. The human remains are accompanied by a label reading "Skull of Cahuilla Tribe Indian-Morong Valley California-Tribe now in Palm Canyon, California, G-Cyrus Belden, 1966." A second label reads "Indian skull from Cahuilla Tribe Morongo Valley and Calif. Now in Palm Canyon Donated by Cyrus Belden St. Petersburg, Fla., and Morongo Valley, Calif 193[?]" The human remains consist of a single cranium lacking the mandible and teeth in the maxilla. Cranial measurements indicate the individual was male. Comparison of the cranial measurements to modern populations using the FORDISC program returned only a broad affiliation of Native American. Comparison with a standard database of older Native American samples identified as Eskimo, Arikara, Peruvian, and Californian (tied to Native populations of the Channel Islands area), showed that the cranium was most similar to the California group. No known individual was identified. No associated funerary objects are present.

An obituary for "Cyrus L. (Cy) Belden" published in local newspapers in 1974 identifies him as a native of New Jersey and a former resident of St. Petersburg, Florida. Belden was apparently residing in Hudson, New Jersey, in 1942, when he filled out a World War II draft registration card. However, his address on the draft card was marked through, and a handwritten entry updated it to one in Monterey Park, California. Newspaper entries, voter registration records, and city directories place Belden in Long Beach,

California, at various dates between 1944 and 1958. He appears to have moved to Florida by 1965. Belden lived in St. Petersburg, Florida, before moving to Tampa three years before his death.

Based on geographical, archeological, oral traditional, and historical lines of evidence, as well as expert opinion, the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California and the Morongo Band of Mission Indians, California [previously listed as Morongo Band of Cahuilla Mission Indians of the Morongo Reservation] (hereafter referred to as "The Tribes") are culturally affiliated with the human remains.

Determinations Made by the Department of Anthropology, University of South Florida

Officials of the Department of Anthropology, University of South Florida have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Thomas J. Pluckhahn, Department of Anthropology, University of South Florida, 4202 E Fowler Avenue, SOC 107, Tampa, FL 33620-8100, telephone (813) 549-9742, email tpluckhahn@usf.edu, by October 27, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Department of Anthropology, University of South Florida is responsible for notifying The Consulted and Invited Tribes that this notice has been published.

Dated: September 21, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021-20912 Filed 9-24-21; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0032655; PPWOCRADNO-PCU00RP14.R50000]

Notice of Inventory Completion: California State University, Sacramento, Sacramento, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The California State University, Sacramento has completed an inventory of associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request to the California State University, Sacramento. If no additional requestors come forward, transfer of control of the associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request with information in support of the request to the California State University, Sacramento at the address in this notice by October 27, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Dianne Hyson, Dean of the College of Social Sciences and Interdisciplinary Studies, California State University, Sacramento, 6000 J Street Sacramento, CA 95819, telephone (916) 278-6504, email dhyson@csus.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of associated funerary objects under the control of the California State University, Sacramento, Sacramento, CA. The associated funerary objects were removed from CA-SAC-16 (also known as the Bennett Mound, Willey Mound, or Mound Ranch) in Sacramento County, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the associated funerary objects was made by the California State University, Sacramento professional staff in consultation with representatives of the Buena Vista Rancheria of Me-Wuk Indians of California; Ione Band of Miwok Indians of California; Kletsel Dehe Band of Wintun Indians [previously listed as Cortina Indian Rancheria]; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; United Auburn Indian Community of the Auburn Rancheria of California; and two non-federally recognized Indian groups, the Miwok Tribe of El Dorado Rancheria and the Nashville-Eldorado Rancheria. The Wilton Rancheria, California and the Yocha Dehe Wintun Nation, California [previously listed as Rumsey Indian Rancheria of Wintun Indians of California] were invited to consult but did not participate. Hereafter, all the above entities are referred to as "The Consulted and Invited Tribes and Groups."

History and Description of the Associated Funerary Objects

On March 15, 2011, human remains and associated funerary objects from site CA-SAC-16 in Sacramento County, CA, were listed in a Notice of Inventory Completion published in the **Federal Register** (76 FR 14052-14054, March 15, 2011). Subsequently, these human remains and objects were repatriated to the Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California. Following repatriation, 428 additional funerary objects associated with the previously repatriated human remains were found in the collections of California State University, Sacramento. They include 425 associated funerary objects from the 1971 Sacramento State College excavation led by Ann Peak and three associated funerary objects from the 1960s American River College excavations directed by Charles Gebhardt (which had been transferred from American River College to California State University Sacramento). The 425 funerary objects from the 1971

excavation are one lot of ash, 11 pieces of baked clay, two shell beads, four lots of charcoal, two pieces of debitage, one edge modified flake, one groundstone fragment, nine invertebrate remains, two pieces of historic metal, two shell ornaments, one unmodified stone, 17 thermally altered rocks, two bird bone tubes, and 370 faunal remains. The three funerary objects from the 1960s excavations are two shell beads and one animal bone.

Temporally diagnostic artifacts recovered from CA-SAC-16 indicate that the site was used from the Middle Horizon up until the early Historic Period. Linguistic evidence suggests that ancestral-Penutian speaking groups related to modern day Miwok, Nisenan, and Patwin groups occupied the region during the Middle (550 B.C.—A.D. 1100) and Late (A.D. 1100—Historic) Horizons, while ethnohistoric and ethnographic sources indicate that the site was most likely historically occupied by Nisenan-speaking groups. Consequently, officials of California State University, Sacramento reasonably believe that the ethnographic, historical, and geographical evidence indicates that the burials and cultural items recovered from Site CA-SAC-16 are most closely affiliated with contemporary descendants of the Nisenan, and have more distant ties to neighboring groups, such as the Plains Miwok and Patwin.

Determinations Made by the California State University, Sacramento

Officials of the California State University, Sacramento have determined that:

- Pursuant to 25 U.S.C. 3001(3)(A), the 428 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the associated funerary objects and the Buena Vista Rancheria of Me-Wuk Indians of California; Ione Band of Miwok Indians of California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; United Auburn Indian Community of the Auburn Rancheria of California; and the Wilton Rancheria, California (hereafter referred to as "The Tribes").

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control

of these associated funerary objects should submit a written request with information in support of the request to Dr. Dianne Hyson, Dean of the College of Social Sciences and Interdisciplinary Studies, California State University, Sacramento, 6000 J Street, Sacramento, CA 95819, telephone (916) 278-6504, email dhyson@csus.edu, by October 27, 2021. After that date, if no additional requestors have come forward, transfer of control of the associated funerary objects to The Tribes may proceed. If joined to a request from one or more of The Tribes, the following non-federally recognized Indian groups may also receive transfer of control of the human remains and associated funerary objects: The Miwok Tribe of El Dorado Rancheria and the Nashville-Eldorado Rancheria.

The California State University, Sacramento is responsible for notifying The Consulted and Invited Tribes and Groups that this notice has been published.

Dated: September 21, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021-20913 Filed 9-24-21; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NAGPRA-NPS0032656; PPWOCRADN0-PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: California State University, Sacramento, Sacramento, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: California State University, Sacramento in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the California State University, Sacramento. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not

identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the California State University, Sacramento at the address in this notice by October 27, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Dianne Hyson, Dean of the College of Social Sciences and Interdisciplinary Studies, California State University, Sacramento, 6000 J Street, Sacramento, CA 95819, telephone (916) 278-6504, email dhyson@csus.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the California State University, Sacramento, Sacramento, CA, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

On March 15, 2011, unassociated funerary objects from site CA-SAC-16 in Sacramento County, CA, were listed in a Notice of Intent to Repatriate published in the **Federal Register** (76 FR 14049-14050, March 15, 2011). Subsequently, these unassociated funerary objects were repatriated to the Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California.

Following repatriation of the objects listed in the 2011 notice, 290 additional unassociated funerary objects were found in the Anthony Zallio collection. Zallio, a local amateur archeologist who collected in the area during the 1920-30s, donated his collection to California State University, Sacramento. The 290 unassociated funerary objects are 269 shell beads, four shell ornaments, and 17 projectile points.

Following repatriation of the objects listed in the 2011 notice, three additional unassociated funerary objects were found among the materials recovered during the 1953 Sacramento State College excavations directed by Dr. Richard Reeve. The three unassociated funerary objects are three shell beads.

Following repatriation of the objects listed in the 2011 notice, two additional unassociated funerary objects were found among the materials recovered during the 1960s American River College excavations directed by Charles Gebhardt. This collection was transferred from American River College to California State University Sacramento at an unknown date. The two unassociated funerary objects are one worked shell with ochre and one modified bone.

Following repatriation of the objects listed in the 2011 notice, an additional 98 unassociated funerary objects were found among the materials recovered during the 1971 Sacramento State College excavations led by Ann Peak. The 98 unassociated funerary objects are 89 vertebrate remains, one shell bead, one invertebrate remain, one groundstone fragment, one thermally altered rock, one lot of charcoal, one obsidian projectile point, one modified bone, and two pieces of baked clay.

Temporally diagnostic artifacts recovered from CA-SAC-16 indicate that the site was used from the Middle Horizon until the early Historic Period. Linguistic evidence suggests that ancestral-Penutian speaking groups related to modern day Miwok, Nisenan, and Patwin groups occupied the region during the Middle (550 B.C.-A.D. 1100) and Late (A.D. 1100-Historic) Horizons. Ethnohistoric and ethnographic sources indicate that the site was most likely historically occupied by Nisenan-speaking groups. In summary, officials of California State University, Sacramento reasonably believe that the ethnographic, historical, and geographical evidence indicates that the historic burials and cultural items recovered from Site CA-SAC-16 are most closely affiliated with contemporary descendants of the Nisenan and are more distantly related to neighboring groups, such as the Plains Miwok and Patwin.

Determinations Made by California State University, Sacramento

Officials of the California State University, Sacramento have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the 393 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group

identity that can be reasonably traced between the unassociated funerary objects and the Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Dr. Dianne Hyson, California State University, Sacramento, 6000 J Street, Sacramento, CA 95819, telephone (916) 278-6504, email dhyson@csus.edu, by October 27, 2021. After that date, if no additional requestors have come forward, transfer of control of the unassociated funerary objects to the Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California may proceed.

California State University, Sacramento is responsible for notifying the Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California that this notice has been published.

Dated: September 21, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021-20914 Filed 9-24-21; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000
211S180110; S2D2S SS08011000
SX064A000 21XS501520; OMB Control
Number 1029-0094]

Notice of Information Collection; Renewal

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before October 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/

PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 4556–MIB, Washington, DC 20240, or by email to mgehlhar@osmre.gov. Please reference OMB Control Number 1029–0094 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at mgehlhar@osmre.gov, or by telephone at (202) 208–2716. You may also view the ICR at <http://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), 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.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on May 28, 2021 (86 FR 28889). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

- (1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;
- (2) The accuracy of our estimate of the burden for this 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) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. 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 information establishes procedures and requirements for terminating jurisdiction of surface coal mining and reclamation operations, petitions for rulemaking, and citizen suits filed under the Surface Mining Control and Reclamation Act of 1977.

Title of Collection: 30 CFR part 700—General.

OMB Control Number: 1029–0094.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State and Tribal governments and individuals.

Total Estimated Number of Annual Respondents: 5.

Total Estimated Number of Annual Responses: 5.

Estimated Completion Time per Response: Varies 1 hour to 50 hours, depending activity.

Total Estimated Number of Annual Burden Hours: 63.

Respondent’s Obligation: Required to obtain or retain a benefit.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: \$0.

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.*).

Mark J. Gehlhar,

*Information Collection Clearance Officer,
Division of Regulatory Support.*

[FR Doc. 2021–20890 Filed 9–24–21; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000
211S180110; S2D2S SS08011000
SX064A000 21XS501520; OMB Control
Number 1029–0098]

Petition Process for Designation of Federal Lands as Unsuitable for All or Certain Types of Surface Coal Mining Operations and for Termination of Previous Designations

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.
ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before October 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 4556–MIB, Washington, DC 20240, or by email to mgehlhar@osmre.gov. Please reference OMB Control Number 1029–0098 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at mgehlhar@osmre.gov, or by telephone at (202) 208–2716. You may also view the ICR at <http://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), 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.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on May 28, 2021 (86 FR 28888). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this 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) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. 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: This part establishes the minimum procedures and standards for designating Federal lands unsuitable for certain types of surface mining operations and for terminating designations pursuant to a petition. The information requested will aid the regulatory authority in the decision-making process to approve or disapprove a request.

Title of Collection: Petition process for designation of Federal lands as unsuitable for all or certain types of surface coal mining operations and for termination of previous designations.

OMB Control Number: 1029–0098.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Individuals.

Total Estimated Number of Annual Respondents: 1.

Total Estimated Number of Annual Responses: 1.

Estimated Completion Time per Response: 1,000 hours.

Total Estimated Number of Annual Burden Hours: 1000.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: \$0.

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.*).

Mark J. Gehlhar,

*Information Collection Clearance Officer,
Division of Regulatory Support.*

[FR Doc. 2021–20892 Filed 9–24–21; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000
211S180110; S2D2S SS08011000
SX064A000 21XS501520; OMB Control
Number 1029–0057]

Reclamation on Private Lands

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before October 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW,

Room 4556–MIB, Washington, DC 20240, or by email to mgehlhar@osmre.gov. Please reference OMB Control Number 1029–0057 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at mgehlhar@osmre.gov, or by telephone at (202) 208–2716. You may also view the ICR at <http://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), 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.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on May 28, 2021 (86 FR 28887). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this 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) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. 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: Public Law 95–87 authorizes Federal, State, and Tribal governments to reclaim private lands and allows for the establishment of procedures for the recovery of the cost of reclamation activities on privately owned lands. These procedures are intended to ensure that governments have sufficient capability to file liens so that certain landowners will not receive a windfall from reclamation.

Title of Collection: Reclamation on Private Lands.

OMB Control Number: 1029–0057.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State and Tribal governments.

Total Estimated Number of Annual Respondents: 1.

Total Estimated Number of Annual Responses: 1.

Estimated Completion Time per Response: 120 hours.

Total Estimated Number of Annual Burden Hours: 120.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: \$0.

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.*).

Mark J. Gehlhar,

*Information Collection Clearance Officer,
Division of Regulatory Support.*

[FR Doc. 2021–20889 Filed 9–24–21; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–903]

Importer of Controlled Substances Application: Groff NA Hemplex, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Groff NA Hemplex, LLC. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before October 27, 2021. Such persons may also file a written request for a hearing on the application on or before October 27, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All request for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on August 13, 2021, Groff NA Hemplex, LLC., 100 Redco Avenue, Suite A, Red Lion, Pennsylvania 17356–1436, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to import the above controlled substances as bulk to manufacture research grade material for clinical trial studies. Several types of Marihuana Extract compounds are listed under drug code 7350. No other activity for these drug codes are authorized for this registration.

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 Food and Drug Administration- approved or non-

approved finished dosage forms for commercial sale.

Brian S. Besser,

Acting Assistant Administrator.

[FR Doc. 2021–20887 Filed 9–24–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OMB Number 1121–0361]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension

AGENCY: SMART Office, Office of Justice Programs, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Office of Justice Programs, SMART Office, 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 November 26, 2021.

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 Samantha Opong, Program Specialist, SMART Office, 810 7th Street NW, Washington, DC 20531, Samantha.Opong@usdoj.gov, (202) 514–9320. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to OIRA_submissions@omb.eop.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the SMART Office, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the

- proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

1. Type of Information Collection: This is a “New collection,” the collection has not previously been used or sponsored by the SMART Office.

The Title of the Form/Collection: Campus Information Sharing and Response Project.

As part of a fellowship project in the Office of Sex Offender Sentencing, Monitoring, Apprehending, Registering, and Tracking (SMART), Office of Justice Programs at the U.S. Department of Justice, the Campus Information Sharing and Response project is exploring how institutions of higher education share, respond and coordinate information to prevent sexual assault perpetration. This project will collect through an online questionnaire information about current practices utilized by colleges and universities with regards to the following:

- Policies and practices regarding registered sex offenders who may be students or employees
- Policies and practices regarding individuals found responsible and sanctioned for campus sexual misconduct policy violations
- Policies and practices used in reviewing criminal or disciplinary sexual misconduct history of prospective or current students

2. The agency form number, if any, and the applicable component of the Department sponsoring the collection: There is no agency form number for this collection. The applicable component within the Department of Justice is the SMART Office.

Affected public who will be asked or required to respond, as well as a brief abstract: The respondents to this collection/affected public includes business or other for profit institutions of higher education, and not-for-profit institutions. The SMART Office is exploring how institutions of higher education share, respond and

coordinate information to prevent sexual assault perpetration. This project will collect information about current policies and practices utilized by colleges and universities regarding registered sex offenders who may be students or employees; individuals found responsible and sanctioned for campus sexual misconduct policy violations; and the review of criminal or disciplinary sexual misconduct history of prospective or current students.

3. An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 50 respondents are estimated, and it will take each respondent approximately 15 minutes to complete the questionnaire.

4. An estimate of the total public burden (in hours) associated with the collection: Based on the estimate of 50 respondents, each taking approximately 15 minutes to complete the questionnaire, the estimated total public burden (in hours) associated with the collection is 12.5 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: September 21, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–20834 Filed 9–24–21; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

United States Marshals Service

[OMB Number 1105–0106]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change of a Currently Approved Collection; Comments Requested: Form CSO–005, Preliminary Background Check Form

AGENCY: U.S. Marshals Service, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), U.S. Marshals Service (USMS), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional 30 days until October 27, 2021.

FOR FURTHER INFORMATION CONTACT:

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension without change of a currently approved collection.

(2) *The Title of the Form/Collection:* Form CSO–005, Preliminary Background Check Form.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number: Form CSO–005.

Component: U.S. Marshals Service, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Court Security Officers/ Special Security Officer (CSO/SSO) Applicants.

Other: [None].

Abstract: The CSO–005 Preliminary Background Check Form is used to

collect applicant information for CSO/SSO positions. The applicant information provided to USMS from the Vendor gives information about which District and Facility the applicant will be working, the applicant's personal information, prior employment verification, employment performance and current financial status. The information allows the selecting official to hire applicants with a strong history of employment performance and financial responsibility. The questions on this form have been developed from the OPM, MSPB and DOJ "Best Practice" guidelines for reference checking.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 750 respondents will utilize the form, and it will take each respondent approximately 60 minutes to complete the 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 750 hours, which is equal to (750 (total # of annual responses) * 60 minutes).

(7) *An Explanation of the Change in Estimates:* N/A.

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: September 21, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021-20820 Filed 9-24-21; 8:45 am]

BILLING CODE 4410-04-P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Disclosures by Insurers to General Account Policyholders

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before October 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202-693-8538, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: Section 1460 of the Small Business Job Protection Act of 1996 (Pub. L. 104-188) (SBJPA) amended the Employee Retirement Income Security Act of 1974 (ERISA) by adding a new section to the statute, 401(c). Regulation section 29 CFR 2550.401(c)-1 imposes specific requirements on insurers that are parties to Transition Policies in order to ensure that the fiduciaries acting on behalf of plans have adequate information and understanding of how the Transition Policies work. Certain of these requirements constitute information collections. Specifically, an insurer that issues and maintains a Transition Policy to or for the benefit of an employee benefit plan must disclose to the plan fiduciary, initially upon issuance of the policy and on an annual basis, to the extent that the policy is not a guaranteed benefit policy: (1) The methods by which income and expenses of the insurer's general account are allocated to the policy, the actual annual return to the plan, and other pertinent information; (2) the extent to which alternative arrangements supported by the assets of the insurer's separate accounts are available; (3) any rights under the policy to transfer funds

to a separate account and the terms governing such right; and (4) the extent to which support by assets of the insurer's separate accounts might pose differing risks to the plan. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 31, 2021 (86 FR 16787).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL-EBSA.

Title of Collection: Disclosures by Insurers to General Account Policyholders.

OMB Control Number: 1210-0114.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 353.

Total Estimated Number of Responses: 26,981.

Total Estimated Annual Time Burden: 114,670 hours.

Total Estimated Annual Other Costs Burden: \$10,792.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: September 21, 2021.

Mara Blumenthal,
Senior PRA Analyst.

[FR Doc. 2021-20954 Filed 9-24-21; 8:45 am]

BILLING CODE 4510-29-P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 21-CRB-0010-AU (iHeartMedia)]

Notice of Intent To Audit

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Public notice.

SUMMARY: The Copyright Royalty Judges announce receipt from SoundExchange,

Inc., of a notice of intent to audit the 2018, 2019, and 2020 statements of account submitted by commercial webcaster iHeartMedia concerning the royalty payments it made pursuant to two statutory licenses.

FOR FURTHER INFORMATION CONTACT: Anita Blaine, CRB Program Specialist, (202) 707-7658, crb@loc.gov.

SUPPLEMENTARY INFORMATION: The Copyright Act, title 17 of the United States Code, grants to sound recordings copyright owners the exclusive right to publicly perform sound recordings by means of certain digital audio transmissions, subject to limitations. Specifically, the right is limited by the statutory license in section 114, which allows nonexempt noninteractive digital subscription services, eligible nonsubscription services, and preexisting satellite digital audio radio services to perform publicly sound recordings by means of digital audio transmissions. 17 U.S.C. 114(f). In addition, a statutory license in section 112 allows a service to make necessary ephemeral reproductions to facilitate digital transmission of the sound recording. 17 U.S.C. 112(e).

Licensees may operate under these licenses provided they pay the royalty fees and comply with the terms set by the Copyright Royalty Judges. The rates and terms for the section 112 and 114 licenses are codified in 37 CFR parts 380 and 382-84.

As one of the terms for these licenses, the Judges designated SoundExchange, Inc., (SoundExchange) as the Collective, *i.e.*, the organization charged with collecting the royalty payments and statements of account submitted by eligible nonexempt noninteractive digital subscription services such as Commercial Webcasters and with distributing the royalties to the copyright owners and performers entitled to receive them under the section 112 and 114 licenses. *See* 37 CFR 380.4(d).

As the Collective, SoundExchange may, only once a year, conduct an audit of a licensee for any or all of the prior three calendar years to verify royalty payments. SoundExchange must first file with the Judges a notice of intent to audit a licensee and deliver the notice to the licensee. *See* 37 CFR 380.6. On September 14, 2021, SoundExchange filed with the Judges a notice of intent to audit iHeartMedia for the years 2018-2020.

The Judges must publish notice in the **Federal Register** within 30 days of receipt of a notice announcing the Collective's intent to conduct an audit. *See* 37 CFR 380.6(c). This notice fulfills

the Judges' publication obligation with respect to SoundExchange's September 14, 2021 notice of intent to audit.

Dated: September 22, 2021.

Jesse M. Feder,
Chief Copyright Royalty Judge.

[FR Doc. 2021-20894 Filed 9-24-21; 8:45 am]

BILLING CODE 1410-72-P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request; NCUA Call Report

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comment.

SUMMARY: The National Credit Union Administration (NCUA), as part of a continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the following revisions of a currently approved collection, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments should be received on or before November 26, 2021 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Dawn Wolfgang, National Credit Union Administration, 1775 Duke Street, Suite 6032, Alexandria, Virginia 22314; email at PRAComments@NCUA.gov. Given the limited in-house staff because of the COVID-19 pandemic, email comments are preferred.

FOR FURTHER INFORMATION CONTACT: Address requests for additional information to Dawn Wolfgang at the address above or telephone 703-548-2279.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133-0004.

Title: NCUA Call Report.

Form: NCUA Form 5300.

Type of Review: Revision of a currently approved collection.

Abstract: Sections 106 and 202 of the Federal Credit Union Act require federally insured credit unions to make financial reports to the NCUA. Section 741.5 prescribes the method in which federally insured credit unions must submit this information to NCUA. NCUA Form 5300, Call Report, is used to file quarterly financial and statistical data through NCUA's online portal, CUOnline.

The financial and statistical information is essential to NCUA in

carrying out its responsibility for supervising federal credit unions. The information also enables NCUA to monitor all federally insured credit unions with National Credit Union Share Insurance Fund (NCUSIF) insured share accounts.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated No. of Respondents: 5,031.

Estimated No. of Responses per Respondent: 4.

Estimated Total Annual Responses: 20,124.

Estimated Burden Hours per Response: 4.

Estimated Total Annual Burden Hours: 80,049.

Reason for Change: The Call Report is being restructured to streamline the schedules, retire obsolete account codes, and accommodate the Risk-Based Capital Ratio Calculation schedule. Revisions are attributed to adding schedules for Off-Balance Sheet Exposures and the Risk-Based Capital Ratio Calculation. Adjustments have been made to the number of respondents due to the decline in the number of federally insured credit unions, which has averaged approximately one percent per quarter.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) Whether the collection of information is necessary for the proper execution of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the 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 the information on the respondents, including the use of automated collection techniques or other forms of information technology.

By Melane Conyers-Ausbrooks, Secretary of the Board, the National Credit Union Administration, on September 21, 2021.

Dated: September 22, 2021.

Dawn D. Wolfgang,
NCUA PRA Clearance Officer.

[FR Doc. 2021-20850 Filed 9-24-21; 8:45 am]

BILLING CODE 7535-01-P

NATIONAL CREDIT UNION ADMINISTRATION

Submission for OMB Review; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice.

SUMMARY: The National Credit Union Administration (NCUA) will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice.

DATES: Comments should be received on or before October 27, 2021 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by contacting Dawn Wolfgang at (703) 548-2279, emailing PRAComments@ncua.gov, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133-0188.

Type of Review: Extension of a currently approved collection.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: This collection of information is necessary to enable the Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency's programs.

Affected Public: Individuals and Households; Private Sector: Businesses or other for-profits and Not-for-profit institutions.

Estimated Total Annual Burden Hours: 42,000.

By Melane Conyers-Ausbrooks, Secretary of the Board, the National Credit Union Administration, on September 21, 2021.

Dated: September 22, 2021.

Dawn D. Wolfgang,

NCUA PRA Clearance Officer.

[FR Doc. 2021-20883 Filed 9-24-21; 8:45 am]

BILLING CODE 7535-01-P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comment.

SUMMARY: The National Credit Union Administration (NCUA), as part of a continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the following extensions of a currently approved collection, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments should be received on or before November 26, 2021 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Dawn Wolfgang, National Credit Union Administration, 1775 Duke Street, Suite 6032, Alexandria, Virginia 22314; email at PRAComments@NCUA.gov. Given the limited in-house staff because of the COVID-19 pandemic, email comments are preferred.

FOR FURTHER INFORMATION CONTACT: Address requests for additional information to Dawn Wolfgang at the address above or telephone 703-548-2279.

SUPPLEMENTARY INFORMATION: OMB Number: 3133-0121.

Title: Notice of Change of Officials and Senior Executive Officers.

Type of Review: Extension of a currently approved collection.

Forms: NCUA Forms 4063 and 4063a.

Abstract: In order to comply with statutory requirements, the agency must obtain sufficient information from new officials or senior executive officers of troubled or newly chartered credit unions to determine their fitness for the position. This is established by the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA), Public Law 101-73. The forms provide a standardize format to collect the information needed.

Affected Public: Private Sector: Not-for-profit institutions; Individual or household.

Estimated No. of Respondents: 183.

Estimated No. of Responses per Respondent: Credit Union 1.48; Individual 1.

Estimated Total Annual Responses: 454.

Estimated Burden Hours per Response: Credit Union 1.45; Individual 2.

Estimated Total Annual Burden Hours: 759.

OMB Number: 3133-0169.

Title: Purchase of Assets and Assumptions of Liabilities.

Type of Review: Extension of a currently approved collection.

Abstract: In accordance with § 741.8, federally insured credit unions (FICUs) must request approval from the NCUA prior to purchasing assets or assuming liabilities of a privately insured credit union, other financial institution, or their successor interest. A FICU seeking approval must submit a letter to the appropriate NCUA Regional Director stating the nature of the transaction and include copies of relevant transaction documents. Relevant transaction documents may include but are not limited to: the credit union's financial statements, strategic plan, and budget, inventory of the assets and liabilities to be transferred, and any relevant contracts or agreements regarding the transfer. NCUA uses the information to determine the safety and soundness of the transaction and risk to the National Credit Union Share Insurance Fund (NCUSIF).

Affected Public: Private Sector: Not-for-profit institutions.

Estimated No. of Respondents: 16.

Estimated No. of Responses per Respondent: 1.

Estimated Total Annual Responses: 16.

Estimated Burden Hours per Response: 120.

Estimated Total Annual Burden Hours: 1,920.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) Whether the collection of information is necessary for the proper execution of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the 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 the

information on the respondents, including the use of automated collection techniques or other forms of information technology.

By Melane Conyers-Ausbrooks, Secretary of the Board, the National Credit Union Administration, on September 21, 2021.

Dated: September 22, 2021.

Dawn D. Wolfgang,

NCUA PRA Clearance Officer.

[FR Doc. 2021–20878 Filed 9–24–21; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit issued.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT:

Polly Penhale, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–8030; email: ACApermits@nsf.gov.

SUPPLEMENTARY INFORMATION: On August 20, 2021, the National Science Foundation published a notice in the *Federal Register* of a permit application received. The permit was issued on September 20, 2021, to:

Permit No. 2022–006

1. Ron Naveen, Oceanites

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2021–20815 Filed 9–24–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation

ACTION: Notice of permit modification issued.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT:

Polly Penhale, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–8030; email: ACApermits@nsf.gov.

SUPPLEMENTARY INFORMATION: On August 20, 2021, the National Science Foundation published a notice in the *Federal Register* of a permit modification request received. The permit modification was issued on September 20, 2021, to:

1. Ron Naveen, Oceanites Permit No. 2019–001

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2021–20819 Filed 9–24–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit modification request received and permit issued.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of a requested permit modification issued.

DATES: November 20, 2019–March 30, 2022.

The permit modification was issued on September 21, 2021.

FOR FURTHER INFORMATION CONTACT:

Polly Penhale, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–7420; email: ACApermits@nsf.gov.

SUPPLEMENTARY INFORMATION: The National Science Foundation (NSF), as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 671), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection.

Description of Permit Modification Requested: The Foundation issued a permit (ACA 2019–012) to Conrad Combrink, Silversea Cruises, Ltd., on November 13, 2018. The issued permit allows the applicant to conduct waste management activities associated with the operation of remotely piloted aircraft systems (RPAs). Cruises engages experienced pilots to fly small, battery-operated, remotely controlled

quadcopter equipped with cameras to capture aerial footage for commercial and educational uses.

On September 19, 2021, Bill Davis, Vice President, Expeditions Operations and Development, Silversea Cruises, Ltd., provided NSF an update based on activities planned for the 2019–2020 field season. Silversea's activities are the same or similar as those detailed in the original permit. The Environmental Officer has reviewed the modification request and has determined that the amendment is not a material change to the permit, and it will have a less than a minor or transitory impact.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2021–20813 Filed 9–24–21; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of September 27, October 4, 11, 18, 25, November 1, 2021.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

MATTERS TO BE CONSIDERED:

Week of September 27, 2021

Thursday, September 30, 2021

9:00 a.m. Strategic Programmatic Overview of the Operating Reactors and New Reactors Business Lines (Public Meeting). (Contact: Candace De Messieres: 301–415–8395)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the web address—<https://video.nrc.gov/>.

Week of October 4, 2021—Tentative

Tuesday, October 5, 2021

10:00 a.m. Meeting with the Advisory Committee on the Medical Uses of Isotopes (Public Meeting). (Contact: Don Lowman: 301–415–5452)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the web address—<https://video.nrc.gov/>.

Friday, October 8, 2021

10:00 a.m. Meeting with the Advisory Committee on Reactor Safeguards

(Public Meeting). (Contact: Larry Burkhart: 301-287-3775)

Additional Information: Due to COVID-19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the web address—<https://video.nrc.gov/>.

Week of October 11, 2021—Tentative

There are no meetings scheduled for the week of October 11, 2021.

Week of October 18, 2021—Tentative

Tuesday, October 19, 2021

10:00 a.m. All Employees Meeting with the Commissioners (Public Meeting). (Contact: Anthony DeJesus: 301-287-9219)

Additional Information: Due to COVID-19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the web address—<https://www.nrc.gov/>.

Week of October 25, 2021—Tentative

Thursday, October 28, 2021

10:00 a.m. Meeting with the Organization of Agreement States and the Conference of Radiation Control Program Directors (Public Meeting). (Contact: Celimar Valentin-Rodriguez: 301-415-7124)

Additional Information: Due to COVID-19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the web address—<https://video.nrc.gov/>.

Week of November 1, 2021—Tentative

There are no meetings scheduled for the week of November 1, 2021.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301-287-3591 or via email at Wesley.Held@nrc.gov. The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: <https://www.nrc.gov/public-involve/public-meetings/schedule.html>.

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (e.g., braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301-287-0745, by videophone at 240-428-3217, or by email at

Anne.Silk@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301-415-1969, or by email at Tyesha.Bush@nrc.gov or Betty.Thweatt@nrc.gov.

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: September 23, 2021.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2021-20986 Filed 9-23-21; 11:15 am]

BILLING CODE 7590-01-P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collection for OMB Review; Comment Request; Special Financial Assistance Information

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to request extension of OMB approval of information collection.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget (OMB) extend approval, without change, under the Paperwork Reduction Act, of a collection of information contained in PBGC's regulation on special financial assistance. This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

DATES: Comments must be submitted on or before November 26, 2021.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Email:* paperwork.comments@pbgc.gov. Refer to OMB control number 1212-0074 in the subject line.
- *Mail or Hand Delivery:* Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005-4026.

Commenters are strongly encouraged to submit public comments electronically. PBGC expects to have limited personnel available to process

public comments that are submitted on paper through mail. Until further notice, any comments submitted on paper will be considered to the extent practicable.

All submissions received must include the agency's name (Pension Benefit Guaranty Corporation, or PBGC) and refer to OMB control number 1212-0074. All comments received will be posted without change to PBGC's website, <http://www.pbgc.gov>, including any personal information provided. Commenters should not include any information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information ("confidential business information"). Submission of confidential business information without a request for protected treatment constitutes a waiver of any claims of confidentiality.

Copies of the collection of information may be obtained by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005-4026, or calling 202-229-4040 during normal business hours. TTY users may call the Federal Relay Service toll-free at 800-877-8339 and ask to be connected to 202-229-4040.

FOR FURTHER INFORMATION CONTACT: Melissa Rifkin (rifkin.melissa@pbgc.gov), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005-4026; 202-229-6563. (TTY and TDD users may call the Federal relay service toll-free at 800-877-8339 and ask to be connected to 202-229-6563.)

SUPPLEMENTARY INFORMATION: Section 4262 of the Employee Retirement Income Security Act of 1974 (ERISA) requires PBGC to provide special financial assistance (SFA) to certain financially troubled multiemployer plans upon application for assistance. To implement section 4262 of ERISA, PBGC added a new part 4262 to its regulations, "Special Financial Assistance by PBGC." Part 4262 provides guidance to multiemployer pension plan sponsors on eligibility, determining the amount of SFA, content of an application for SFA, the process of applying, PBGC's review of applications, restrictions and conditions, and reporting and notice requirements.

To apply for SFA, a plan sponsor must file an application with PBGC and include information about the plan, plan documentation, and actuarial information, as specified in §§ 4262.6 through 4262.9. PBGC needs this

information to review a plan's eligibility for SFA, priority group status (if applicable), and amount of requested SFA. PBGC estimates that over the next 3 years an annual average of 60 plan sponsors will file applications for SFA with an average annual hour burden of 600 hours and an average annual cost burden of \$1,800,000.

Under § 4262.16(i), a plan sponsor of a plan that has received SFA must file an Annual Statement of Compliance with the restrictions and conditions under section 4262 of ERISA and part 4262 once every year through 2051. PBGC needs the information in the Annual Statement of Compliance to ensure that a plan is compliant with the imposed restrictions and conditions. PBGC estimates that over the next 3 years an annual average of 49 plan sponsors will file Annual Statements of Compliance with an average annual hour burden of 98 hours and an average annual cost burden of \$117,600.

Under § 4262.15(c), a plan sponsor of a plan with benefits that were suspended under sections 305(e)(9) or 4245(a) of ERISA must issue notices of reinstatement to participants and beneficiaries whose benefits were suspended and are being reinstated. Participants and beneficiaries need the notice of reinstatement to better understand the calculation and timing of their reinstated benefits and, if applicable, make-up payments. PBGC estimates that over the next 3 years an average of 11 plans per year will be required to send notices to participants with suspended benefits. PBGC estimates that these notices will impose an average annual hour burden of 22 hours and average annual cost burden of \$22,667.

Finally, under § 4262.16(d), (f), and (h) a plan sponsor must file a request for a determination from PBGC for approval for an exception under certain circumstances for SFA conditions under § 4262.16 relating to reductions in contributions, transfers or mergers, and settlement of withdrawal liability. PBGC needs the information required for a request for determination to determine whether to approve an exception from the specified condition of receiving SFA. PBGC estimates that beginning in 2023, PBGC will receive an average of 2.2 requests per year for determinations. PBGC estimates an average annual hour burden of 2.53 hours and average annual cost burden of \$6,333.

The estimated aggregate average annual hour burden for the next 3 years for the information collection in part 4262 is 723 hours for employer and fund office administrative, clerical, and supervisory time. The estimated

aggregate average annual cost burden for the next three years for the information collection request in part 4262 is \$1,946,600, for approximately 4,867 contract hours assuming an average hourly rate of \$400 for work done by outside actuaries and attorneys. The actual hour burden and cost burden per plan will vary depending on plan size and other factors.

The collection of information under the regulation has been approved by OMB under control number 1212-0074 (expires January 31, 2022). PBGC intends to request that OMB extend its approval for 3 years. 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.

PBGC is soliciting public comments to—

- 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 methodologies and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses.

Issued in Washington, DC, by:

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2021-20893 Filed 9-24-21; 8:45 am]

BILLING CODE 7709-02-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m. on Wednesday, September 29, 2021.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

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.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at <https://www.sec.gov>.

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.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION:

For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551-5400.

Dated: September 22, 2021.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2021-20967 Filed 9-23-21; 11:15 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93095; File No. SR-ICEEU-2021-017]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the ICE Clear Europe Delivery Procedures

September 21, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

(“Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on September 15, 2021, ICE Clear Europe Limited (“ICE Clear Europe” or the “Clearing House”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule changes described in Items I, II and III below, which Items have been prepared primarily by ICE Clear Europe. ICE Clear Europe filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b–4(f)(4)(ii)⁴ thereunder, such that the proposed rule was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed amendments is for ICE Clear Europe to amend its Delivery Procedures (the “Delivery Procedures”) relating to German natural gas futures contracts traded on the ICE Endex market in connection with the merger of two existing natural gas market areas in Germany, operated by NetConnect Germany GmbH & Co. and NetConnect Germany Management GmbH (together “NCG”) and GASPOOL Balancing Services GmbH (“GASPOOL”), with the resulting combined market area to be called the “Trading Hub Europe” (“THE”). The German market area merger is currently planned to take effect on October 1, 2021 (at which time the amendments discussed herein would take effect).

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

In connection with the merger of the market areas of the German gas transmission system operators with GASPOOL and NCG, ICE Clear Europe is proposing certain amendments to its Delivery Procedures relating to German natural gas futures contracts traded on ICE Endex, in order to be consistent with related changes made by the exchange and to give effect to the German market merger. As has been announced by ICE Endex,⁵ the existing German GASPOOL Natural Gas Futures Contract will cease to be listed with the September 2021 contract month, and the existing German NCG Natural Gas Futures Contract will continue to trade on ICE Endex and will be renamed the German THE Natural Gas Futures Contract. Accordingly, ICE Clear Europe is proposing to delete the content of Part G of the Delivery Procedures (relating to the ICE Endex GASPOOL Natural Gas Futures Contracts) and replace it with “[NOT USED]”. The amendments would also remove the reference to ICE Endex GASPOOL Natural Gas Futures Contracts in section 5.1. ICE Clear Europe is also proposing to amend Part H of its Delivery Procedures to reflect the change of the contract name to ICE Endex German THE Natural Gas Futures instead of ICE Endex NCG Natural Gas Futures Contracts and make certain other amendments related to the merger of market areas as discussed herein. All references to ICE Endex NCG Natural Gas Futures Contracts in the Delivery Procedures would be replaced with references to ICE Endex German THE Natural Gas Futures Contracts and references to NCG Rules would be replaced with references to THE Rules.

In connection with the above, multiple additional conforming amendments would be made throughout Part H to reference relevant THE terms, documents and systems reflecting the combined German gas market operation. Specifically, references to the term “NCG” would be deleted and replaced with the term “THE”, which would be defined specifically to be Trading Hub Europe GmbH domiciled in Ratingen and Berlin, the operator of the market area cooperation between all gas network owners in Germany known as “THE” or any successor thereto.

References to the term, “NCG’s Communication Facilities” would be

replaced with references to “THE’s Communication Facilities”. This term would reference THE’s electronic facility, which includes any electronic facility which enables the submission of a Trade Nomination to THE through the portal, any web-based communication channel including the related functionality and connected systems provided by THE, “Communications Systems” within the meaning of the THE Rules, and access to information concerning the submitted Trade Nominations, and any successor system thereto.

The term, “THE Balancing Group Contract”, which means the THE’s Balancing Group Contract Terms and Conditions, would be added.

The term, “THE Rules”, would replace the term “NetConnect Germany (NCG) Rules”, and would mean the Electricity and Gas Supply Act, the Gas Network Access rules and THE Balancing Group Contract, and any manuals, procedures, practices and directions of THE supporting its operation.

A new Section 3.2 would be added to state explicitly that the Transmission System, THE and THE’s Communication Facilities constitute “Delivery Facilities” for the purposes of Rule 101 of the Rules. The limitations on liability would also be expanded and clarified to provide that neither the Buyer nor the Seller nor their Transferees or Transferors would have any claim against the Clearing House for losses resulting from (a) actions taken by the Clearing House pursuant to the THE Rules or (b) technical issues, the condition or operation of or the performance of the Transmission System, THE or THE’s Communication Facilities except as otherwise expressly provided in the ICE Endex Rules (expanding upon more limited references in the current procedure to the Transmission System or NCG).

The Delivery Timetable for routine deliveries set out in section 5 would be updated such that the submission of delivery intentions for the ICE Endex German THE Natural Gas Futures and the nomination of the Transferor/ Transferee must be made by 11:30 CET instead of 13:00 CET.

A note would also be added stating that the delivery timetables for routine and failed deliveries could be altered without notice at the discretion of the Clearing House, consistent with other existing provisions of Parts G and H, and clarifying that such modifications could be made in the event of technical issues or other conditions relating to THE, among other reasons.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(a).

⁴ 17 CFR 240.19b–4(f)(4)(ii).

⁵ See ICE Endex Circulars E21/026, E20/039 and E21/014, available at <https://www.theice.com/endex/circulars>.

(b) Statutory Basis

Section 17A(b)(3)(F) of the Act⁶ requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest. The proposed amendments are intended to update the Delivery Procedures to reflect changes in the trading of natural gas futures contracts on ICE Endex in light of the merger of the market areas of the German gas transmission system operators with GASPOOL and NCG. The resulting ICE Endex German THE Natural Gas Futures Contract will continue to be cleared by the Clearing House in the substantially same manner as the current NCG contract, with modifications to reflect the merger of the underlying gas market, and will be supported by ICE Clear Europe's existing financial resources, risk management, systems and operational arrangements. Accordingly, ICE Clear Europe believes that its financial resources, risk management, systems and operational arrangements are sufficient to support clearing of such contracts and to manage the risks associated with such contracts. As a result, in ICE Clear Europe's view, the amendments would be consistent with the prompt and accurate clearance and settlement of the contracts, and the protection of investors and the public interest consistent with the requirements of Section 17A(b)(3)(F) of the Act.⁷ (In ICE Clear Europe's view, the amendments would not affect the safeguarding of funds or securities in the custody or control of the clearing agency or for which it is responsible, within the meaning of Section 17A(b)(3)(F).⁸)

In addition, Rule 17Ad-22(e)(10)⁹ requires that each covered clearing agency establish and maintain transparent written standards that state its obligations with respect to the delivery of physical instruments, and establish and maintain operational practices that identify, monitor and manage the risks associated with such physical deliveries. As discussed above, the amendments would incorporate into the Delivery Procedures the

amendments necessary to address the merger of the market areas of the German gas transmission system operators with GASPOOL and NCG into THE. The resulting ICE Endex German THE Futures Contract will continue to be cleared in substantially the same manner as the current NCG contract, supported by ICE Clear Europe's existing financial resources, risk management, systems and operational arrangements. The amendments would also remove Part G and related references related to the GASPOOL contracts that will no longer be traded on ICE Endex as a result of the underlying market merger. As a result, ICE Clear Europe believes the amendments are consistent with the requirements of Rule 17Ad-22(e)(10).¹⁰

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The changes are being proposed in order to update the Delivery Procedures in connection with the merger of the market areas of the German gas transmission system operators with GASPOOL and NCG. The terms of clearing are not otherwise changing. ICE Clear Europe does not believe the amendments would adversely affect competition among Clearing Members, materially affect the cost of clearing, adversely affect access to clearing in the new contracts for Clearing Members or their customers, or otherwise adversely affect competition in clearing services. Accordingly, ICE Clear Europe does not believe that the amendments would impose any impact or burden on competition that is not appropriate in furtherance of the purpose of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any comments 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 has become effective pursuant to Section 19(b)(3)(A)

of the Act¹¹ and paragraph (f) of Rule 19b-4¹² thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, security-based swap submission or advance notice 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-ICEEU-2021-017 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-ICEEU-2021-017. 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 filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at <https://>

⁶ 15 U.S.C. 78q-1(b)(3)(F).

⁷ 15 U.S.C. 78q-1(b)(3)(F).

⁸ 15 U.S.C. 78q-1(b)(3)(F).

⁹ 17 CFR 240.17Ad-22(e)(10).

¹⁰ 17 CFR 240.17Ad-22(e)(10).

¹¹ 15 U.S.C. 78s(b)(3)(A).

¹² 17 CFR 240.19b-4(f).

www.theice.com/clear-europe/regulation.

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-ICEEU-2021-017 and should be submitted on or before October 18, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-20817 Filed 9-24-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93097; File No. SR-FINRA-2021-015]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving a Proposed Rule Change To Amend FINRA Rules 1210 (Registration Requirements) and 1240 (Continuing Education Requirements)

September 21, 2021.

I. Introduction

On June 3, 2021, the Financial Industry Regulatory Authority, Inc. (“FINRA”) filed with the Securities and Exchange Commission (“SEC” or “Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Exchange Act”) ¹ and Rule 19b-4 thereunder,² a proposed rule change to amend FINRA Rules 1240 (Continuing Education Requirements) and 1210 (Registration Requirements) to, among other things, (1) require that the Regulatory Element of FINRA’s continuing education program for registered persons of FINRA members (“CE Program”) be tailored to each registration category and completed annually rather than every three years and (2) provide a way for individuals to maintain their qualifications following the termination of registration through continuing education. The proposed rule change was published for comment in the **Federal Register** on June 24,

2021.³ On July 23, 2021, FINRA consented to extend until September 22, 2021, the time period in which the Commission must approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.⁴ On August 12, 2021, FINRA responded to the comment letters received in response to the Notice.⁵ This order approves the proposed rule change.

II. Description of the Proposed Rule Change

A. Background

As discussed in the Notice, FINRA’s CE Program is codified under Rule 1240. The CE Program currently requires registered persons to complete continuing education consisting of a Regulatory Element and a Firm Element.⁶ The Regulatory Element, which is administered by FINRA, focuses on regulatory requirements and industry standards,⁷ while the Firm Element is provided by each firm and focuses on, among other things, securities products, services and strategies the firm offers, firm policies, and industry trends.⁸ FINRA is proposing to amend Rule 1240 and make conforming amendments to Rule 1210 to modify aspects of both the Regulatory Element and the Firm Element.⁹

³ See Exchange Act Release No. 92183 (Jun. 15, 2021), 86 FR 33427 (Jun. 24, 2021) (File No. SR-FINRA-2021-015) (“Notice”).

⁴ See letter from Afshin Atabaki, Special Advisor and Associate General Counsel, FINRA, to Edward Schellhorn, Special Counsel, Division of Trading and Markets, Commission, dated July 23, 2021. This letter is available at <https://www.finra.org/sites/default/files/2021-07/SR-FINRA-2021-015-Extension1.pdf>.

⁵ See letter from Afshin Atabaki, Special Advisor and Associate General Counsel, FINRA, to Vanessa Countryman, Secretary, Commission, dated August 12, 2021, 2021 (“FINRA Letter”). The FINRA Letter is available at <https://www.sec.gov/comments/sr-finra-2021-015/srfinra2021015-9135950-247347.pdf>.

⁶ See FINRA Rule 1240. See also FINRA Rule 1210.07 (All Registered Persons Must Satisfy the Regulatory Element of Continuing Education).

⁷ FINRA’s website describes the Regulatory Element as being focused on compliance, regulatory, ethical and sales practice standards. According to FINRA, its content is derived from industry rules and regulations, and accepted standards and practices in the industry. Moreover, participants must demonstrate proficiency in order to satisfy the continuing education requirements. See <https://www.finra.org/registration-exams-ce/continuing-education#regulatory>.

⁸ See Notice, 86 FR at 33428.

⁹ FINRA stated that the proposed rule change was developed in close consultation with the Securities Industry/Regulatory Council (“CE Council”) and discussions with stakeholders, including the North American Securities Administrators Association (“NASAA”). Specifically, FINRA stated that the proposed changes to the CE Program are based in

In addition, FINRA stated in the Notice that it and the CE Council also plan to enhance the CE Program in other ways that do not require changes to FINRA’s rules.¹⁰ Among other things, FINRA and the CE Council will work together to incorporate a variety of instructional formats (including a mobile-compatible format) and provide firms with advance notice of Regulatory Element topics as well as additional resources and guidance to help firms develop effective Firm Element training programs.¹¹

B. Transition to an Annual Regulatory Element for Each Registration Category

Currently, FINRA Rule 1240(a) initially requires a registered person to complete the applicable Regulatory Element within 120 days after the person’s second registration anniversary date and, thereafter, within 120 days after every third registration anniversary date.¹² FINRA’s proposed rule change would amend FINRA Rule 1240(a) and Rule 1210.07 to require registered persons to complete the Regulatory Element of the CE Program annually by December 31. Firms, however, would have the flexibility to require their registered persons to complete the Regulatory Element sooner than December 31, which would allow firms to coordinate the timing of the Regulatory Element with other training requirements, including the Firm Element.¹³ Similarly, the proposed rule change would preserve FINRA’s ability to extend the time by which a registered person must complete the Regulatory Element for good cause shown if requested in writing and with supporting documentation.¹⁴ Consistent

part on the CE Council’s September 2019 recommendations to enhance the CE Program. See Notice, 86 FR at 33429.

¹⁰ See Notice, 86 FR at 33428.

¹¹ See *id.*

¹² See FINRA Rule 1240(a)(1).

¹³ See Notice, 86 FR at 33429. FINRA also stated that individuals who would be registering as a representative or principal for the first time on or after the implementation date of the proposed rule change would be required to complete their initial Regulatory Element for that registration category in the next calendar year following their registration. In addition, subject to specified conditions, individuals who would be reregistering as a representative or principal on or after the implementation date of the proposed rule change would also be required to complete their initial Regulatory Element for that registration category in the next calendar year following their reregistration. See *id.* at 33429.

¹⁴ See proposed Rule 1240(a)(2). See also Notice, 86 FR at 33429. FINRA may also grant conditional examination waivers requiring individuals to complete the Regulatory Element by a specified date. Non-registered individuals who are participating in the Financial Services Affiliate Waiver Program (“FSAWP”) under Rule 1210.09

¹³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

with current requirements, individuals who fail to complete their Regulatory Element within the prescribed period would be automatically designated as “CE inactive”¹⁵ in the Central Registration Depository (“CRD”) system¹⁶ until the requirements of the Regulatory Element have been satisfied.¹⁷

FINRA stated that the current content of the Regulatory Element is broad in nature, applying to both representatives and principals in a single format that leads individuals through a story depicting scenarios that they may encounter in the course of their work.¹⁸ The proposed rule change would instead tailor the content of the Regulatory Element to each registration category. Thus, registered persons would be required to complete content specifically designed for each representative or principal registration category that they hold.¹⁹

FINRA’s proposed rule change also proposes to amend Rule 1240(a) to include five additional elements such that: (1) Individuals who are designated as CE inactive would be required to complete all of their pending and upcoming annual Regulatory Element, including any annual Regulatory

Element that becomes due during their CE inactive period, to return to active status;²⁰ (2) the two-year CE inactive period would be calculated from the date individuals become CE inactive, and would continue to run regardless of whether individuals terminate their registrations;²¹ (3) individuals who become subject to a significant disciplinary action may be required to complete assigned continuing education content as prescribed by FINRA;²² (4) individuals who have not completed any Regulatory Element content for a registration category in the calendar year(s) prior to reregistering would not be approved for registration for that category until they complete that Regulatory Element content, pass an examination for that registration category, or obtain an unconditional examination waiver for that registration category, whichever is applicable;²³ and (5) the Regulatory Element requirements would apply to individuals who are registered, or are in the process of registering as a representative or principal.²⁴

FINRA stated that moving to an annual Regulatory Element requirement that is tailored to each registration category would further the goals of the Regulatory Element by helping ensure that registered persons are better trained in more recent regulatory issues, allowing them to perform their work in a more compliant and effective manner.²⁵ For instance, FINRA stated that transitioning to an annual Regulatory Element cycle would help ensure that registered persons receive more frequent assessments on current issues and better understand recent regulatory changes.²⁶ Specifically, FINRA stated that registered persons would be current on issues and regulatory changes that would enable them to perform their work in a more compliant and effective manner than would otherwise be possible with Regulatory Element training taking place only once every three years under the current CE Program.²⁷ According to FINRA, this enhanced timeliness and relevance of the Regulatory Element would reduce firms’ regulatory risk as well as enhancing compliance and reducing compliance-related costs.²⁸

C. Recognition of Other Training Requirements for Firm Element and Extension of Firm Element to All Registered Persons

Currently, Rule 1240(b) requires a firm to develop and administer an annual Firm Element training program for its covered registered persons.²⁹ The Firm Element must, at a minimum, include training in ethics and professional responsibility, as well as training in the following items concerning securities products, services, and strategies offered by the member: (1) General investment features and associated risk factors; (2) suitability and sales practice considerations; and (3) applicable regulatory requirements.³⁰ Firms are required to conduct an annual needs analysis to, at minimum, determine the appropriate Firm Element training for covered registered persons at the firm based on the specific business of the member, and then provide the Firm Element training annually.³¹ The current rule does not expressly recognize other required training, such as training relating to the anti-money laundering (“AML”) compliance program and training relating to the annual compliance meeting, for purposes of satisfying the Firm Element training.³²

FINRA’s proposed rule change would amend Rule 1240(b) to allow for recognition of the successful completion of existing firm training programs relating to the AML compliance program and the annual compliance meeting toward satisfying an individual’s annual Firm Element requirement.³³ The proposed rule change would also amend the rule to extend the Firm Element requirement to all registered persons, including individuals who maintain solely a permissive registration consistent with Rule 1210.02, thereby further aligning the Firm Element requirement with other broadly-based training requirements.³⁴ FINRA also is

(“FSAWP Participants”) are also subject to the Regulatory Element. See Notice, 86 FR at 33428.

¹⁵ See proposed Rule 1240(a)(2). A CE inactive person is prohibited from performing, or being compensated for, any activities requiring FINRA registration, including supervision. Additionally, if registered persons remain CE inactive for two consecutive years, they must requalify by retaking required examinations (or obtain a waiver of the applicable qualification examinations). See Notice, 86 FR at 33428.

¹⁶ See <https://www.finra.org/registration-exams-ce/classic-crd>. As stated on the website, FINRA integrated the registration filing functionality that supports the CRD Program into FINRA Gateway, available at <https://www.finra.org/filing-reporting/finra-gateway>. The standalone CRD features were retired August 21, 2021.

¹⁷ See Notice, 86 FR at 33428.

¹⁸ See *id.* FINRA stated that the Regulatory Element currently consists of a subprogram for registered persons generally, and a subprogram for principals and supervisors. According to FINRA, while some of the current Regulatory Element content is unique to particular registration categories, most of the content has broad application to both representatives and principals. FINRA also stated that the Regulatory Element was originally designed at a time when most individuals had to complete the Regulatory Element at a test center, and its design was shaped by the limitations of the test center-based delivery model. Since 2015, FINRA has transitioned the delivery of the Regulatory Element to an online platform (“CE Online”), which allows individuals to complete the content online at a location of their choosing, including their private residence. According to FINRA, the transition to CE Online has enhanced FINRA’s ability to update continuing education content in a timelier fashion and to develop content that is tailored to each registration category as well as to present the materials in an optimal learning format. See *id.*

¹⁹ See proposed Rules 1240(a)(1) and (a)(4).

²⁰ See Notice, 86 FR at 33429–30.

²¹ See Notice, 86 FR at 33430.

²² See *id.*

²³ See Notice, 86 FR at 33430.

²⁴ See *id.*

²⁵ See Notice, 86 FR at 33434.

²⁶ See *id.*

²⁷ See *id.*

²⁸ See *id.*

²⁹ See Rule 1240(b). See also Notice, 86 FR at 33428. The rule defines “covered registered persons” as any registered person who has direct contact with customers in the conduct of a member’s securities sales, trading and investment banking activities, any individual who is registered as an Operations Professional or a Research Analyst, and the immediate supervisors of any such persons. See Rule 1240(b)(1).

³⁰ See Rule 1240(b). See also Notice, 86 FR at 33428.

³¹ See Rule 1240(b). See also Notice, 86 FR at 33428.

³² See Rule 3310(e) and Rule 3110(a)(7). See also Notice, 86 FR at 33429.

³³ See proposed Rule 1240(b)(2)(D). See also Notice, 86 FR at 33430.

³⁴ See proposed Rule 1240(b)(1). See also Notice, 86 FR at 33430.

proposing to modify the current minimum training criteria under Rule 1240(b) to provide that Firm Element training must cover topics related to the role, activities, or responsibilities of the registered person, as well as professional responsibility.³⁵

FINRA stated that the proposed rule change would further enhance and streamline the Firm Element requirement.³⁶ Specifically, FINRA stated that the inclusion of an express recognition of existing firm training programs, such as the annual compliance meeting or AML training, toward satisfying an individual's Firm Element requirement would help firms conserve compliance resources currently devoted to duplicative training programs.³⁷ Additionally, FINRA stated that the extension of the Firm Element requirement to all registered persons would help ensure that firms enhance the securities knowledge, skill, and professionalism of all registered persons.³⁸ FINRA stated that it would also ensure that registered persons are provided more specific learning materials relevant to their day-to-day activities.³⁹

D. Maintenance of Qualification After Termination of Registration

Currently, individuals whose registrations as representatives or principals have been terminated for two or more years may reregister as representatives or principals only if they requalify by retaking and passing the applicable representative- or principal-level examination or if they obtain a waiver of such examination(s) (the "two-year qualification period").⁴⁰ The proposed rule change would not eliminate the two-year qualification period. Instead, the proposed rule change would amend the rules governing requalification of registered representatives who have terminated their registration to provide individuals an alternative means of maintaining their qualifications and staying current on their regulatory and securities knowledge following the termination of a registration, subject to conditions and

limitations outlined in further detail below.⁴¹

Specifically, the proposed rule change would adopt paragraph (c) under Rule 1240, and Supplementary Material .01 and .02 to Rule 1240, to provide eligible individuals who terminate any of their representative or principal registrations the option of maintaining their qualification for any of the terminated registrations for up to five years by completing continuing education.⁴² This optional program would be limited by the following conditions: (1) Individuals would be required to be registered in the terminated category for at least one year immediately prior to the termination of the category;⁴³ (2) individuals could elect to participate when they terminate a registration or within two years from the termination of a registration;⁴⁴ (3) individuals would be required to complete annually all prescribed continuing education;⁴⁵ (4) individuals would have a maximum of five years in which to reregister;⁴⁶ (5) individuals who have been CE inactive for two consecutive years, or who become CE inactive for two consecutive years during their participation, would not be eligible to participate or continue;⁴⁷ and (6) individuals who are subject to a statutory disqualification, or who become subject to a statutory disqualification following the termination of their registration or during their participation, would not be eligible to participate in, or continue with, the program.⁴⁸

⁴¹ See Notice, 86 FR at 33430. Eligible individuals who elect not to participate in the proposed continuing education program to maintain their qualifications would continue to be subject to the two-year qualification period.

⁴² See proposed Rule 1240(c) and Supplementary Material .01 and .02 to Rule 1240. See also Notice, 86 FR at 33430.

⁴³ See Notice, 86 FR at 33430.

⁴⁴ See *id.* FINRA stated that individuals who elect to participate at the later date would be required to complete, within two years from the termination of their registration, any continuing education that becomes due between the time of their Form U5 submission and the date that they commence their participation. In addition, FINRA stated that it plans to enhance its systems to notify individuals of their eligibility to participate, enable them to affirmatively opt in, and notify them of their annual continuing education requirement if they opt in. See *id.*

⁴⁵ See Notice, 86 FR at 33431. FINRA's proposed rule change would also allow FINRA to grant an extension of time for the participant to complete the prescribed continuing education following a participant's request in writing with supporting documentation and a showing of good cause. See *id.*

⁴⁶ See Notice, 86 FR at 33431.

⁴⁷ See *id.*

⁴⁸ See *id.* In addition, FINRA stated that any continuing education content completed in furtherance of this proposed program would be retroactively nullified upon disclosure of the statutory disqualification. See *id.*

FINRA also is proposing two additional provisions in the proposed rule change. The first is a look-back provision that would, subject to specified conditions, extend the application of the proposed five-year option to individuals who have been registered as a representative or principal within two years immediately prior to the implementation date of the proposed rule change and individuals who have been FSAWP Participants immediately prior to the implementation date of the proposed rule change.⁴⁹ The second is a re-eligibility provision that would allow individuals to regain eligibility to participate in the proposed five-year continuing education option each time they reregister with a firm for a period of at least one year and subsequently terminate their registration, provided that they satisfy the other participation conditions and limitations.⁵⁰

FINRA also is proposing conforming amendments to Rule 1210, including adding references to proposed Rule 1240(c) under Rule 1210.08.⁵¹

According to FINRA, the continuing education content for participants of the proposed five-year continuing education option would consist of a combination of Regulatory Element content and content selected by FINRA and the CE Council from the Firm Element content catalog discussed further below.⁵² The content would correspond to the registration category for which individuals wish to maintain their qualifications.⁵³ The proposed rule change would also provide that the continuing education content for participants of the proposed five-year continuing education option must be completed annually by December 31

⁴⁹ See Notice, 86 FR at 33431. Among other things, proposed Supplementary Material .01 to Rule 1240 and proposed Rule 1210.09 would provide the requirements and limitations to participation in this optional five-year continuing education period for FSAWP Participants, including when they would need to elect to participate, when they would need to complete their initial annual content, and adjustment of their initial participation period based on the date that their registration was terminated. Additionally, FINRA stated that while the current waiver program for FSAWP Participants would not be available to new participants upon implementation of the proposed rule change, individuals who are FSAWP Participants immediately prior to the implementation date of the proposed rule change could elect to continue in that waiver program until the program has been retired. The proposed rule change would preserve FINRA's ability to extend the time by which FSAWP Participants must complete the Regulatory Element for good cause shown under proposed Rule 1240(a)(2). See Notice, 86 FR at 33431.

⁵⁰ See Notice, 86 FR at 33431.

⁵¹ See *id.*

⁵² See *id.*

⁵³ See *id.*

³⁵ See proposed Rule 1240(b)(2)(B). See also Notice, 86 FR at 33430.

³⁶ See Notice, 86 FR at 33434.

³⁷ See *id.*

³⁸ See Notice, 86 FR at 33438.

³⁹ See *id.*

⁴⁰ See Rule 1210.08 (Lapse of Registration and Expiration of SIE). FINRA also stated that the current two-year qualification period before an individual would need to retest and pass their examinations was adopted prior to the creation of the CE Program and was intended to ensure that individuals who reregister are relatively current on their regulatory and securities knowledge. See Notice, 86 FR at 33429.

each year, consistent with the proposed annual Regulatory Element provision.⁵⁴ In addition, FINRA stated that participants who are maintaining their qualification status for a principal registration category that includes one or more corequisite representative registrations would also need to complete required annual continuing education for the corequisite registrations in order to maintain their qualification status for the principal registration category.⁵⁵

FINRA stated that the proposed rule change would: (1) Incentivize individuals to stay current on their respective securities industry knowledge following the termination of any of their registrations; (2) promote investor protection given that the individuals availing themselves of this optional program would be subjected to continuing education that is as rigorous as the continuing education of registered persons, while providing an opportunity for the securities industry to retain skilled and experienced workers; (3) increase flexibility for individuals to address life and career events and necessary absences from registered functions without having to requalify each time; and (4) enhance diversity and inclusion in the securities industry by attracting and retaining a broader and diverse group of professionals.⁵⁶ FINRA has also stated that it plans to evaluate the efficacy of the proposed rule change following its implementation to ensure that it is meeting its goals.⁵⁷

E. Other Enhancements to the CE Program

FINRA stated in the Notice that it intends to make additional enhancements to the CE Program that will not require changes to FINRA rules.⁵⁸ FINRA stated that it would work with the CE Council to incorporate a variety of instructional formats to present the Regulatory Element content, including via a mobile compatible

application.⁵⁹ In addition, FINRA stated that it would work with the CE Council to publish in advance the Regulatory Element learning topics for the next year so that firms may review those topics when developing their Firm Element training plan to avoid unnecessary duplication of topics if desired.⁶⁰ Given that the proposed rule change would transition to an annual Regulatory Element requirement, FINRA stated that it would assist firms with compliance with that requirement by enhancing its systems to provide firms and registered persons with additional notification, management, and tracking functionality.⁶¹

FINRA also stated that it would improve the guidance and resources available to firms to develop effective Firm Element training programs, such as updated guidance for developing and documenting training plans and specific principles.⁶² Further, FINRA stated that it would work with the CE Council to develop a catalog of continuing education content that would serve as an optional resource for firms to select relevant Firm Element content and create learning plans for their registered persons.⁶³ According to FINRA, the catalog would include content developed by third-party training providers, FINRA, and the other Self-Regulatory Organizations participating in the CE Program.⁶⁴

F. Effective Date

If the Commission approves the proposed rule change, FINRA will announce the implementation dates of the proposed rule change in a Regulatory Notice to be published no later than 90 days following Commission approval.⁶⁵

⁵⁹ See *id.* In response to a Regulatory Notice that FINRA issued concerning proposed changes to the CE Program, it received a comment letter encouraging FINRA to make continuing education available via a mobile application. FINRA stated that it intends to take that suggestion and plans to make the Regulatory Element content available via a mobile application. See FINRA Letter at 2–3.

⁶⁰ See Notice, 86 FR at 33432.

⁶¹ See *id.* FINRA stated that the transition to an annual Regulatory Element requirement would have the effect of increasing the number of registered persons who would be required to complete the Regulatory Element on an annual basis. As such, FINRA stated that the enhancement of notification, modification, and tracking functionality in its systems will be helpful for firms and individuals. See Notice, 86 FR at 33432.

⁶² See Notice, 86 FR at 33432.

⁶³ See Notice, 86 FR at 33432, 33434. FINRA stated that firms would have the option of using the content in this catalog for purposes of their Firm Element training and would not be obligated to select content from the catalog.

⁶⁴ See Notice, 86 FR at 33432.

⁶⁵ See *id.*

III. Discussion and Commission Findings

After careful review of the proposed rule change, the comment letters, and FINRA's response to the comments, the Commission finds that the proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder that are applicable to a national securities association.⁶⁶ Specifically, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Exchange Act, which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.⁶⁷

A. Transition to Annual Regulatory Element for Each Registration Category

As stated above, FINRA is proposing to amend Rule 1240(a) and Rule 1210.07 to require registered persons to complete the Regulatory Element of the CE Program annually by December 31 and to require registered persons to complete the Regulatory Element content that is tailored for each representative or principal registration category that they hold.

Most commenters were supportive of FINRA's proposed rule change.⁶⁸ One such commenter stated that it appreciated that member firms would be allowed greater flexibility to administer the Regulatory Element in conjunction with other training requirements.⁶⁹ Another cited: (1) The flexibility it would afford in allowing firms to complete training prior to December 31; (2) its availability to individuals via mobile application; and (3) that the proposed Regulatory Element would still require a comparable amount of overall continuing education as it did prior to the proposed rule change.⁷⁰

⁶⁶ In approving this rule change, the Commission has considered the rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

⁶⁷ 15 U.S.C. 78o–3(b)(6).

⁶⁸ See letter from James Rabenstein, Vice President and Chief Compliance Officer, Nationwide Office of the Chief Legal Officer, Nationwide Financial Services, Inc. ("NFS"), dated July 13, 2021 ("NFS Letter"); letter from Lisa Hopkins, NASAA President, General Counsel, and Senior Deputy Commissioner of Securities, West Virginia, NASAA, dated July 14, 2021 ("NASAA Letter"); letter from Kevin Zambrowicz, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association ("SIFMA"), dated July 14, 2021 ("SIFMA Letter").

⁶⁹ See SIFMA Letter at 2.

⁷⁰ See NFS Letter at 1. The NFS Letter also suggested that it would be helpful for the

One commenter, although generally supportive of the proposed rule change, expressed concern that moving to an annual Regulatory Element may increase overall costs and burdens, both for firms and registered persons, associated with an annual increase in required training.⁷¹ The commenter also suggested that the proposed transition from the current three-year cycle to an annual requirement may not be necessary.⁷² Alternatively, the commenter suggested that any transition be done in two phases: (1) From three years to two years to determine if its objectives were met; and then (2) from two years to one year.⁷³

In response, FINRA stated that the overall amount of training in a three-year period would remain approximately the same as the amount of training currently undertaken by completing the Regulatory Element once every three years.⁷⁴ Additionally, FINRA explained that the impact on individuals from increased training requirements, such as the time commitment associated with those trainings, would be limited in that the overwhelming majority of registered persons only hold a single registration category.⁷⁵

With respect to the commenter's proposed transition period, FINRA responded that it believes that a phased implementation with different timing requirements for any of the proposed components would be overly complex and cause confusion. Additionally, FINRA stated that a phased approach would require more resources and could result in greater costs to keep multiple varying Regulatory Element systems and programs running, including potential

additional costs to firms to track and manage differing requirements.⁷⁶ For these reasons, FINRA declined to amend the proposed rule change in response to the commenter's concerns.

In addition, one commenter opposed the proposed change to increase the frequency of the Regulatory Element, believing that it would have a disparate impact on members of underrepresented populations who may have more limited access to a broadband or high-speed internet connection.⁷⁷ The commenter also stated that a mobile compatible format may not be adequate for continuing education given that mobile devices may not meet all learning needs, and that potential access and connectivity challenges will also make this an insufficient solution.⁷⁸ By contrast, a separate commenter was fully supportive of FINRA making the Regulatory Element available via a mobile-compatible format on the grounds that it would simplify the process for individuals that have terminated their registration and wanted to reenter the industry at some point in their career.⁷⁹

In response, FINRA stated that it specifically tailored the proposed rule change to help meet the individual needs of registered persons and firms.⁸⁰ Accordingly, FINRA stated that the Regulatory Element would be designed to deliver content in a manner that is broadly accessible and compatible with the diverse needs of individuals and their learning needs.⁸¹ In developing the mobile-compatible format, which includes a mobile responsive design, FINRA intends mobile device users to be able to easily, quickly, and intuitively navigate the Regulatory

Element content.⁸² FINRA has committed to developing the mobile application so that access to the training material and the overall learning experience is engaging and intuitive for users such that it would be a comparable to those taking the training on a desktop.⁸³ FINRA believes that these enhancements and the availability of mobile compatibility would address the potential access and diversity concerns that the commenter raised.⁸⁴ Furthermore, FINRA explained that it has made available in the past, and will continue to do so in the future, additional options for individuals who may need or prefer other solutions to fulfill their Regulatory Element content obligations.⁸⁵ For instance, FINRA stated that the Regulatory Element training would also be accessible in other convenient ways, including through a computer or other device at a firm location or on various widely available public and community locations where computer and broadband internet access is available for free.⁸⁶ For these reasons, FINRA declined to amend the proposed rule change in response to the commenter's concerns.

The Commission finds that the proposed rule change to move to an annual Regulatory Element training with content tailored to an individual's representative or principal registration categories is designed to protect investors and is in the public interest. The Commission finds that the rule is reasonably designed to minimize the potential adverse impact on firms and their registered persons. Furthermore, increasing the timeliness of registered persons' training, as well as the relevance of the training's content by tailoring it to each registration category that they hold, would enhance their education and compliance with their regulatory obligations.

The Commission further finds that a shift to an annual Regulatory Element training is more advantageous when compared to the current CE Program in which some existing registered persons may not receive consistent updated

Regulatory Element topics to be published by October 1 of each year. FINRA stated that it would publish the topics by no later than October 1 of each year in order to provide firms with sufficient time to review the Regulatory Element topics for each upcoming year. *See* FINRA Letter at 2 n.4.

⁷¹ *See* letter from Brian Egwele, dated July 2, 2021 ("Egwele Letter"). FINRA also identified that the cost of changing to an annual Regulatory Element generally would increase with the number of representatives at a firm and thus would be higher in aggregate at a larger firm. However, FINRA stated that economies of scale likely exist in the application of the proposed requirements such that the average additional cost of implementing this proposal per representative at larger firms would likely be lower than at smaller firms. *See* Notice, 86 FR at 33435.

⁷² *See* Egwele Letter (expressing support for the proposed rule change by stating that, even though the proposed rule change may increase administrative workload and costs, the "price is worth it to remain compliant.").

⁷³ *See* Egwele Letter.

⁷⁴ *See* Notice, 86 FR at 33430.

⁷⁵ *See* Notice, 86 FR at 33435. According to FINRA, individuals with more than one registration category account for approximately 35 percent of all registered persons.

⁷⁶ *See* FINRA Letter at 3. FINRA also stated that the proposed rule change includes several interrelated annual Regulatory Element components: (1) Annual Regulatory Element content for registered persons; (2) annual Regulatory Element content for non-registered individuals who are participating in the waiver program under FINRA Rule 1210.09; and (3) annual Regulatory Element content for individuals who elect to maintain their qualification status for a terminated registration category. *See id.*

⁷⁷ *See* letter from John Watts, Senior Vice President and Chief Counsel, PFS Investments, Inc. ("PFS"), dated July 15, 2021 ("PFS Letter"). As noted above, the delivery of the Regulatory Element is available through CE Online, which allows individuals to complete the content online at a location of their choosing, including their private residence. *See supra* note 19. Additionally, FINRA and the CE Council have committed to making the annual Regulatory Element content available to users via a mobile application. *See supra* note 60.

⁷⁸ *See id.*

⁷⁹ *See* NFS Letter at 2 (also expressing support for FINRA's intention to publish learning topics in advance on the grounds that it would be helpful for securities industry professionals).

⁸⁰ *See* FINRA Letter at 3.

⁸¹ *See id.*

⁸² *See* FINRA Letter at 4 (FINRA committed to structuring and formatting the Regulatory Element content to ensure that mobile device users have a comparable experience to that of a desktop user even in low bandwidth conditions).

⁸³ *See* FINRA Letter at 4.

⁸⁴ *See* FINRA Letter at 3–4. Additionally, FINRA stated that it remains committed to understanding specific technology or access needs and to provide potential solutions. *See* FINRA Letter at 4.

⁸⁵ *See* FINRA Letter at 4.

⁸⁶ *See id.* FINRA offers individuals the option of completing their Regulatory Element session at test centers in various locations of every state as well as internationally. *Id.*

training from regulators on regulatory developments for up to three years. More specifically, transitioning to an annual Regulatory Element requirement, rather than taking a phased approach, should enhance a firm's regulatory compliance, and reduce a firm's overall regulatory risk because of the increased timeliness and relevance of the more tailored content provided through an annual Regulatory Element training. Additionally, the Commission also finds that the proposed rule change would allow firms to maintain some flexibility for administering the annual Regulatory Element given that firms may require their registered persons to complete the annual requirement earlier than December 31 each year so as to coincide with other training requirements. The Commission also finds that FINRA has reasonably determined that its proposed mobile accessibility would provide a flexible, accessible, and effective learning experience for users who choose to access the Regulatory Element through mobile technology. The proposed mobile application compatibility would also likely allow for a more diverse candidate pool by allowing individuals to reenter or remain in the workforce if they have previously completed the required examinations and have already proven themselves worthy, as suggested by a commenter.⁸⁷ Moreover, to the extent registered persons need or prefer an alternative to mobile compatibility to fulfill their Regulatory Element obligations, FINRA is committed to making alternative options available. As outlined above, these additional options include widely-available test centers as well as public and community locations where computer and broadband access is available for free. The Commission finds that FINRA has provided reasonable solutions to address commenter concerns on accessibility.

Accordingly, for the reasons set forth above, the Commission finds that the proposed rule change is designed to protect investors and is in the public interest.

B. Recognition of Other Training Requirements for Firm Element and Extension of Firm Element Training to All Registered Persons

As stated above, FINRA's proposed rule change would amend Rule 1240(b) to allow for recognition of the successful completion of existing firm training programs relating to the AML compliance program and the annual compliance meeting toward satisfying an individual's annual Firm Element

requirement. The proposed rule change would also amend the rule to extend the Firm Element training requirement to all registered persons, including individuals who maintain solely a permissive registration consistent with Rule 1210.02, thereby further aligning the Firm Element requirement with other broadly-based training requirements.

A number of commenters addressed the Firm Element training component of FINRA's proposed rule change. Most commenters supported allowing the Firm Element to recognize a firm's AML compliance training and annual compliance meeting as fulfilling that requirement.⁸⁸ One commenter stated that it appreciated that the Firm Element would recognize other trainings that members provide to their registered persons.⁸⁹ Another commenter supported this proposal because (1) requiring training to cover "topics related to the role, activities or responsibilities of the registered person"⁹⁰ and (2) requiring members to develop written training plans that are evaluated annually⁹¹ should mitigate any concerns that AML compliance and annual compliance meeting trainings would simply be substituted for more tailored training requirements.⁹²

One commenter stated, however, that a firm's annual needs analysis and written training plan should not need to be recompleted every year if the firm has not changed business models.⁹³ Additionally, the commenter recommended that FINRA consider making the Regulatory Element training the primary, if not the sole means, by which securities industry personnel are made aware of important rules and issues.⁹⁴

In response, FINRA stated that the Firm Element, which is firm-specific and may vary from firm-to-firm, is a necessary component of the CE Program, complementing the Regulatory Element, which ensures that registered persons receive uniform and comprehensive training from regulators on regulatory developments.⁹⁵ Similarly, FINRA stated that even if a firm's business model has not changed, the regulatory or industry developments that may have taken place still necessitate an annual needs analysis to

account for changes in addressing products, services, or strategies offered by the firm.⁹⁶ For these reasons, FINRA declined to amend the proposed rule change to eliminate the Firm Element component of its CE Program in response to the commenter's concerns.

The Commission finds that proposed Rule 1240(b), which expressly allows firms to consider training relating to their AML compliance program and the annual compliance meeting toward satisfying an individual's annual Firm Element requirement, combined with the proposed rule's provision to extend the Firm Element requirement to all registered persons, reasonably aligns the Firm Element requirement with other required training.

The proposed rule change would allow firms to satisfy the Firm Element requirement with important, pre-existing AML compliance training and annual compliance meetings, which should reduce otherwise duplicative training programs for firms. In addition, extending the Firm Element requirement to all registered persons at the firm, including those with permissive registrations, would also help to ensure a better trained and more compliant securities workforce, which is to the advantage of the investing public. Furthermore, the Commission finds that FINRA's determination to retain the Firm Element of its CE program and the obligation that firms conduct an annual needs analysis and written training plan, even in the absence of any new regulatory or industry developments year-to-year, is reasonable.⁹⁷ For these reasons, the Commission finds that the proposed rule change is designed to protect investors and is in the public interest.

C. Maintenance of Qualification After Termination of Registration

As stated above, subject to certain conditions, proposed Rule 1240(c), and Supplementary Material .01 and .02 to Rule 1240, would provide eligible individuals who terminate any of their representative or principal registrations the option of maintaining their qualification for any of their terminated registrations for up to five years without having to requalify by examination or having to obtain an examination waiver by completing continuing education.⁹⁸

Most commenters expressed overall support for FINRA's proposal to allow registered persons to maintain their

⁸⁸ See NFS Letter at 1; SIFMA Letter at 2; NASAA Letter at 1–2.

⁸⁹ See SIFMA Letter at 2.

⁹⁰ Proposed Rule 1240(b)(2)(B).

⁹¹ See proposed Rule 1240(b)(2)(A).

⁹² See NASAA Letter at 1–2.

⁹³ See Letter from Anonymous, dated July 1, 2021 ("Anonymous Letter").

⁹⁴ See Anonymous Letter.

⁹⁵ See FINRA Letter at 5.

⁹⁶ See *id.*

⁹⁷ See *id.*

⁹⁸ See proposed Rule 1240(c) and Supplementary Material .01 and .02 to Rule 1240. See also Notice, 86 FR at 33430.

⁸⁷ See NFS Letter at 2.

qualifications for up to five years through continuing education without the need for reexamination after termination of a registration.⁹⁹ One commenter stated that the proposed change is one step in the process to achieving greater diversity and inclusion in the securities industry by reducing unnecessary barriers to reentry.¹⁰⁰

Several commenters, however, expressed a preference for a longer period of time that an individual could maintain their qualifications following termination of a registration, instead of the five-year period that FINRA proposed.¹⁰¹ One of those commenters strongly supported this aspect of the proposal as a welcome and necessary improvement to continuing education, but preferred a seven-year period of time to maintain qualifications so as to more closely align with the existing seven-year period in the FSAWP program.¹⁰² Other commenters suggested that a seven-year period would be ideal in order to further enhance the diversity benefits of this proposed rule change.¹⁰³ Another commenter supported a longer period to maintain qualifications, especially for individuals who are active within the securities industry in a non-registered

capacity who could be “grandfathered in” rather than needing to go through a waiver process that the commenter described as “onerous” and “subjective.”¹⁰⁴

In response, FINRA stated that it believes the proposed participation period of up to five years would serve the diversity and inclusion goals of the proposed rule change while still providing the appropriate level of training for registered persons and protection for investors.¹⁰⁵ In particular, FINRA believes that this proposal would help attract and retain a broader, more diverse population of individuals to the securities industry by offering a program that is sufficiently flexible to meet the individual needs of registered persons and firms.¹⁰⁶ Moreover, FINRA believes that limiting this option to five years would help ensure that individuals’ knowledge of the industry does not become outdated.¹⁰⁷

FINRA also stated, however, that the proposed five-year maintenance option is not intended to address every situation in which an individual terminates a registration and subsequently decides to reregister.¹⁰⁸ FINRA explained it has always provided an individual who continues to work in the securities industry or a field ancillary to the securities industry the ability to request an examination waiver following a significant absence from a registered role or function.¹⁰⁹ For the above reasons, FINRA believes that the proposed new five-year maintenance period is appropriate.¹¹⁰

Although FINRA declined to amend the participation period at this time, FINRA stated that it would continue to monitor the efficacy of the proposed CE Program, which will include a review of the participation period.¹¹¹

One commenter, although supporting the proposed rule change, also

suggested that, if the rule change is adopted, FINRA should enhance CRD to allow states that have not revised existing regulations to efficiently process registration applications of persons who maintain their qualifications beyond two years.¹¹² In response, FINRA recognized the benefits to the industry of having further alignment between FINRA qualification requirements and state licensing requirements.¹¹³ Thus, FINRA stated that it would work with NASAA and state regulators to provide for an appropriate process and system to allow states to track and process registration requests for individuals operating under the two- or five-year examination provisions.¹¹⁴

The Commission finds that FINRA’s proposed Rule 1240(c), and proposed Supplementary Material .01 and .02 to Rule 1240, is in the public interest and would protect investors because it would, among other things, help enhance the education of registered persons and their compliance with their regulatory obligations, thus reducing regulatory risk. In particular, by providing a means for individuals to maintain their qualifications after termination of a registration for a longer period of time, the proposed rule change would aid the securities industry in attracting and retaining a more diverse workforce. Additionally, this proposed rule change would provide registered persons with increased flexibility to manage significant life events, including professional changes and development (such as pursuing educational goals, a career change to a role in the firm that is not part of the broker-dealer, working overseas for an extended period due to a career change or an attempt at a different career path) or personal life events (such as birth or adoption of a child, unexpected loss in the family or relocation due to family needs). In addition, the Commission finds that FINRA’s decision to choose five years as the time period for maintaining qualifications after termination of a registration, while also continuing to monitor the efficacy of the proposed CE Program, is reasonable.

The proposed rule change would also increase opportunities for reentry to the securities industry for individuals who may not have otherwise been able to do so without retaking their qualification examinations. As a result, this proposed rule change would provide firms with a more diverse pool of applicants from under-represented populations in the

⁹⁹ See SIFMA Letter at 2; NASAA Letter at 2; NFS Letter at 2; letter from Frederick Greene, Executive Vice President, Woodforest Wealth Strategies, dated July 11, 2021 (“Woodforest Letter”); letter from Carrie Chelko, Chief Compliance Officer, Fidelity Investments, dated July 14, 2021 (“Fidelity Letter”); and letter from Howard Spindel, Senior Managing Director, Integrated Solutions, dated July 14, 2021 (“Integrated Letter”).

¹⁰⁰ See SIFMA Letter at 2.

¹⁰¹ See Fidelity Letter at 2; Integrated Letter at 2–3; NFS Letter at 2; and Woodforest Letter at 1.

¹⁰² See Fidelity Letter at 2.

¹⁰³ See NFS Letter at 2; Woodforest Letter at 1–2. Additionally, the Woodforest Letter suggested that individuals availing themselves of this program should be required to complete at least the minimum Firm Element requirement, including training on ethics, AML, regulations, and products and, if applicable, additional continuing education relating to supervisory functions. In response, FINRA stated that the continuing education content for individuals who elect the proposed option would consist of a combination of Regulatory Element content and content selected by FINRA and the CE Council from the Firm Element content catalog. According to FINRA, that content would correspond to the registration category, including any supervisory or principal registration category, for which individuals wish to maintain their qualifications. In addition, FINRA stated that the content selected from the Firm Element content catalog would be based on the minimum standards for Firm Element training, including training in professional responsibility. See FINRA Letter at 6. Commenters were supportive of the content catalog, stating that it would enable more timely and increased awareness that would enhance customer protection, for example, by providing relevant information regarding, among other things, trends in retail investor trading, regulatory rule changes, and cybersecurity. See NASAA Letter at 1. See also Fidelity Letter at 1.

¹⁰⁴ See Integrated Letter at 2–3.

¹⁰⁵ See FINRA Letter at 6. See also Notice, 86 FR at 33435 (explaining that FINRA believes a length of five years could achieve the main goals and anticipated benefits of the proposed changes to the CE Program. FINRA further stated that a seven-year period may not best protect investors and that a five-year period may better mitigate the impact of differences with state licensing requirements.).

¹⁰⁶ See FINRA Letter at 3.

¹⁰⁷ See Notice, 86 FR at 33435–36.

¹⁰⁸ See FINRA Letter at 6.

¹⁰⁹ See *id.* FINRA further stated that in determining whether to grant a waiver in such cases, FINRA expressly considers whether the individual was previously registered, and for how long relative to the duration of time that the individual has been unregistered. FINRA also explained that it considers whether the individual worked in a field ancillary to the securities industry, and for how long, while unregistered. See *id.*

¹¹⁰ See FINRA Letter at 6.

¹¹¹ See Notice, 86 FR at 33431.

¹¹² See NASAA Letter at 2.

¹¹³ See FINRA Letter at 6.

¹¹⁴ See FINRA Letter at 5–6.

securities industry, such as female and older registrants. In turn, this proposed rule change would allow the industry to retain expertise from skilled individuals, providing investors with the advantage of greater experience among the individuals working in the industry. For these reasons, the Commission finds the proposed rule change is designed to protect investors and is in the public interest.

IV. Conclusion

It is therefore ordered pursuant to Section 19(b)(2) of the Exchange Act¹¹⁵ that the proposed rule change (SR-FINRA-2021-015), be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹⁶

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-20818 Filed 9-24-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270-660, OMB Control No. 3235-0722]

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:
Form 1-U

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 this request for extension of the previously approved collection of information discussed below.

Form 1-U (17 CFR 239.93) is used to file current event reports by Tier 2 issuers under Regulation A, an exemption from registration under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*). Form 1-U provides information to the public within four business days of fundamental changes in the nature of the issuer's business and other significant events. We estimate that approximately 144 issuers file Form 1-U annually. We estimate that Form 1-U takes approximately 5.0 hours to prepare. We estimate that 85% of the 5.0

hours per response is prepared by the company for a total annual burden of 612 hours (4.25 hours per response × 144 responses).

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 background documentation for this information collection at the following website: www.reginfo.gov. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) www.reginfo.gov/public/do/PRAMain and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: PRA_Mailbox@sec.gov.

Dated: September 22, 2021.

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-20904 Filed 9-24-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-93094; File No. SR-BOX-2021-14]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing of Amendment No. 1 and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, in Connection With the Proposed Establishment of BSTX as a Facility of the Exchange

September 21, 2021.

On June 7, 2021, BOX Exchange LLC ("Exchange" or "BOX") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to adopt rules in connection with the establishment of the Boston Security Token Exchange LLC ("BSTX") as a facility of the Exchange. The proposed rule change was published for comment in the **Federal Register** on June 24, 2021.³ On August 3, 2021, pursuant to

Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵ On September 16, 2021, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change as originally filed.⁶ The Commission has received no comments on the proposed rule change. The Commission is publishing this notice and order to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons, and to institute proceedings pursuant to Section 19(b)(2)(B) of the Act⁷ to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 92556, 86 FR 43572 (August 9, 2021). The Commission designated September 22, 2021, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change.

⁶ In Amendment No. 1, the Exchange revised the proposal to: (1) Adopt the BSTX LLC Third Amended and Restated Limited Liability Company Agreement ("BSTX LLC Agreement") prior to the commencement of operations of BSTX as a facility of the Exchange, which, among other things, (a) changes the legal name of the facility from "Boston Security Token Exchange LLC" to "BSTX LLC," (b) modifies certain defined terms, including "BSTX Product" and "Competing Business," (c) defines the term "Governmental Authority" and modifies certain provisions to permit access to certain confidential information by any such authority, and (d) adds a provision that would, among other things, require an effective rule filing pursuant to Section 19 of the Exchange Act prior to any Member, or Related Person of such Member, becoming a BSTX Participant if such Member, alone or together with any Related Persons of such Member, has the right to appoint more than 20% of the BSTX Directors entitled to vote; (2) provide additional information about ownership of non-voting Class B Units; (3) clarify how limitations on voting of interests in BOX Holdings are implemented by reallocating voting rights to other BOX Holdings owners, and how a similar provision in the BSTX LLC Agreement would operate; (4) discuss certain provisions and associated definitions in the BSTX LLC Agreement that are the same or different from those that currently apply to BOX Holdings and BOX Options, particularly with respect to the board structure, intellectual property, and automatic admission of Class B Units as Members; (5) provide additional description of limitations on voting and ownership of interests in the Exchange; (6) provide additional description of the roles, obligations, and authorities of BOX Digital, tZERO, and the Exchange with respect to BSTX; (7) describe the funding of operations of BSTX; (8) clarify representation of BSTX Participants on the Exchange's Board and committees, and how those representatives would be appointed at the commencement of operations; and (9) make other technical, clarifying and conforming changes. Amendment No. 1 is available on the Commission's website at: <https://www.sec.gov/comments/sr-box-2021-14/srbox202114-9251558-250847.pdf>.

⁷ 15 U.S.C. 78s(b)(2)(B).

¹¹⁵ 15 U.S.C. 78s(b)(2).

¹¹⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 92206 (June 17, 2021), 86 FR 33402 ("Notice").

I. The Exchange's Description of the Proposed Rule Change, as Modified by Amendment No. 1

The Exchange proposes to establish BSTX⁸ as a facility of the Exchange. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at <http://boxoptions.com>.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is submitting this Proposed Rule Change to the Commission in connection with the proposed establishment of BSTX as a facility of the Exchange, as that term is defined in Section 3(a)(2) of the Act.⁹ Pending trading rules filed as part of a separate rule filing pursuant to the rule filing process under Section 19 of the Act and approved by the Commission, BSTX will operate the BSTX Market.¹⁰ The Proposed Rule Change is to establish BSTX as a facility of the Exchange and, without trading rules approved by the Commission, will not permit BSTX to commence operations of the BSTX Market. However, the approval of the Proposed Rule Change, and BSTX as a facility of the Exchange, will trigger the regulatory oversight responsibilities of the Exchange with respect to BSTX.

BSTX is controlled jointly by BOX Digital, a Delaware limited liability company and a subsidiary of BOX

Holdings Group LLC, and tZERO Group, Inc., a Delaware corporation and an affiliate of Overstock.com, Inc. BSTX is an affiliate of the Exchange and, when approved as a facility of the Exchange, will be subject to regulatory oversight by the Exchange. In addition, the Exchange will enter into a facility agreement with BSTX (the "Facility Agreement") pursuant to which the Exchange will regulate the Company as a facility of the Exchange. The Exchange's powers and authority under the Facility Agreement ensure that the Exchange has full regulatory control over BSTX, which is designed to prevent any owner of BSTX from exercising undue influence over the regulated activities of the Company. The Exchange will also provide certain business services to the Company such as providing human resources and office technology support pursuant to an administrative services agreement between the Exchange and BSTX.

The LLC Agreement is the source of governance and operating authority for the Company and, therefore, functions in a similar manner as articles of incorporation and bylaws would function for a corporation. The Exchange submitted a separate filing to establish rules relating to trading on BSTX.¹¹ The Exchange also submitted a separate filing to introduce structural changes to the Exchange to accommodate regulation of BSTX in addition to the Exchange's existing facility,¹² which was approved (the "Multiple Facilities Filing").¹³ With the addition of BSTX as a facility of the Exchange, BSTX Participants¹⁴ will have the same representation, rights and responsibilities as Exchange Facility Participants¹⁵ on the Exchange's other facility.

¹¹ See BSTX Rulebook Proposal.

¹² Currently, there is only one facility of the Exchange, BOX Options Market LLC.

¹³ See Securities Exchange Act Release No. 88934 May 22, 2020, 85 FR 32085 May 28, 2020.

¹⁴ A BSTX Participant is a firm or organization that is registered with the Exchange pursuant to Exchange Rules for the purposes of participating in Trading on the BSTX Market as an order flow provider or market maker. "Trading" means the availability of the BSTX System to authorized users for entering, modifying, and canceling orders of BSTX Products. "BSTX System" means the technology, know-how, software, equipment, communication lines or services, services and other deliverables or materials of any kind as may be necessary or desirable for the operation of the BSTX Market. "BSTX Product" means a Security, as defined in the Exchange Rules, trading on the BSTX System. "Exchange Rules" means the rules of the Exchange that constitute the 'rules of an exchange' within the meaning of Section 3 of the Act, and that pertain to the BSTX Market. "BSTX Market" means the market operated by BSTX. See Section 1.1, LLC Agreement.

¹⁵ "Exchange Facility Participant" means a firm or organization that is registered with the Exchange pursuant to the Exchange Rules for purposes of

The Exchange currently operates BOX Options Market LLC ("BOX Options"), which is a facility of the Exchange, as that term is defined in Section 3(a)(2) of the Act. The proposed LLC Agreement provisions are generally the same as the provisions of the Amended and Restated Limited Liability Company Agreement of BOX Options Market LLC, dated as of August 15, 2018 (the "BOX Options LLC Agreement") or, where indicated herein, are the same as provisions of the Second Amended and Restated Limited Liability Company Agreement of BOX Holdings, dated as of September 13, 2018, as amended (the "BOX Holdings LLC Agreement").¹⁶ Currently, BOX Holdings has nine separate, unaffiliated owners. BOX Holdings owns 100% of BOX Options so BOX Holdings is essentially the alter ego of BOX Options. By contrast, the Company has two separate, unaffiliated voting owners, BOX Digital and tZERO, each of which owns 50% of the voting class of equity of the Company. Ownership diverges for BOX Options directly above BOX Holdings in its ownership structure and ownership diverges for the Company directly above the Company in its ownership structure. Therefore, as discussed below, when comparing various provisions in the LLC Agreement, some provisions are more appropriately compared with the BOX Holdings LLC Agreement, particularly with respect to ownership issues. The Exchange believes that governance consistent with established provisions that have already received Commission approval harmonizes rules and practices across the Exchange's facilities, which may foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, consistent with Section 6(b)(5) of the Act.¹⁷

Structure of the Company

In the discussion below, the Exchange describes provisions in the LLC Agreement related to the structure of the

participating in trading on any Exchange Facility. See the Second Amended and Restated Limited Liability Company Agreement of BOX Exchange LLC, dated as of May 29, 2020, as amended, (the "Exchange LLC Agreement") Section 1.1.

¹⁶ The Exchange notes, as further described in the Proposed Rule Change, that certain provisions of the BOX Holdings LLC Agreement and BOX Options LLC Agreements are not included in the LLC Agreement because they are not applicable. For example, certain provisions in the BOX Holdings LLC Agreement that are related to different voting classes of ownership are not present in the LLC Agreement because BSTX has only one voting class of ownership. See, e.g., Sections 4.1, 4.4, 4.13 and 7 of the BOX Holdings LLC Agreement.

¹⁷ 15 U.S.C. 78f(b)(5).

⁸ The Company's current legal name is Boston Security Token Exchange LLC and its legal name will be changed to BSTX LLC prior to adoption of the LLC Agreement and commencement of operations.

⁹ 15 U.S.C. 78c(a)(2).

¹⁰ See Securities Exchange Act Release No. 92017 (May 25, 2021), 86 FR 29634 (June 2, 2021) ("BSTX Rulebook Proposal").

Company, highlighting areas that vary in comparison to the BOX Options LLC Agreement and/or the BOX Holdings LLC Agreement and provides the statutory basis for such variation.

Ownership interests of the Company are represented by Units.¹⁸ The Company has two classes of Units: Class A Units¹⁹ and Class B Units.²⁰ Except as otherwise provided in the LLC Agreement, all Units are identical to each other and accord the holders thereof the same obligations, rights, and privileges as accorded to each other holder thereof.²¹ The duly admitted holders of Units are referred to as the members of the Company (“Members”). The Units represent equity interests in the Company and entitle the duly admitted holders thereof to participate in the Company’s allocations and distributions. Voting Class A Units are held 50/50 by BOX Digital and tZERO with each having an economic interest of over 45% in the Company. Non-voting Class B Units are held by various officers, directors, agents, and employees of the Company, each of whom holds less than 5% economic interest in the Company.²² Accordingly, no single Member can unilaterally exert control over the Company. Pursuant to Section 1.1 of the LLC Agreement, a record of the Members is maintained by

the Secretary of the Company and updated from time to time as necessary and as provided in the LLC Agreement (“Membership Record”).²³ These provisions are substantially the same as those in the BOX Holdings LLC Agreement.²⁴

BOX Digital is a subsidiary of BOX Holdings and an affiliate of the Exchange and, therefore, the Company will be an affiliate of the Exchange. BOX Holdings owns 98% of BOX Digital and 2% of BOX Digital is held by Lisa Fall. BOX Holdings already owns one subsidiary that is an existing facility of the Exchange. The existing facility—BOX Options—operates a market for trading option contracts on U.S. equities. BOX Holdings is the parent company for both BOX Digital and BOX Options. BOX Holdings has nine separate, unaffiliated owners, including MX US 2, Inc. (“MXUS2”), a wholly owned, indirect subsidiary of TMX Group Limited (“TMX”), which holds 42.62% of the outstanding units of BOX Holdings, IB Exchange Corp. (“IB”), which holds 22.69% of the outstanding units of BOX Holdings, and Citadel Securities Principal Investments LLC (“Citadel”), which holds 13.80%. The other six owners of BOX Holdings, Citigroup Financial Products Inc., UBS Americas Inc., CSFB Next Fund Inc., LabMorgan Corp., Wolverine Holdings, L.P. and Aragon Solutions Ltd, each hold less than 10% of the outstanding units of BOX Holdings.

Owners of BOX Holdings (“BOX Holdings Members”) hold Class A and Class B Units (together, “Holdings Units”).²⁵ Holdings Units represent equal units of economic rights in BOX Holdings. Voting rights of BOX Holdings Members generally follow the ownership percentage (the “Holdings Ownership Percentage”) based on the ratio of the number of Holdings Units held by each BOX Holdings Member to the total number of Holdings Units issued and outstanding.²⁶ As discussed above, the Holdings Ownership Percentage of each BOX Holdings Member greater than 10% is as follows: MXUS2: 42.62%; IB: 22.69% and Citadel: 13.80%.

However, Exchange Facility Participants are limited to a maximum

of 20% voting power for votes of BOX Holdings Members and votes of directors appointed by an Exchange Facility Participant on the BOX Holdings board of directors.²⁷ IB holds a Holdings Ownership Percentage greater than 20% and therefore, as an Exchange Facility Participant, is limited to voting power with respect to BOX Holdings of no greater than 20%. As a result, IB’s voting power with respect to votes of BOX Holdings Members that would otherwise be greater than 20% is counted for quorum purposes and voted by the person presiding over quorum and vote matters in the same proportion as the remainder of the vote. This limitation effectively automatically reallocates IB’s voting power above 20% to the other BOX Holdings Members and, as a result, each of the other BOX Holdings Members has greater voting power at BOX Holdings than its Holdings Ownership Percentage. The respective voting power of each BOX Holdings Member that is greater than 10% is as follows: MXUS2: 44.10%; IB: 20.00% and Citadel: 14.28%.

Further, one BOX Holdings Member, Wolverine Holdings, L.P. (“Wolverine”), does not currently have a right to designate a director to the BOX Holdings board of directors, where the voting power of each director is tied to the voting power of the BOX Holdings Member that appointed such director.²⁸ As a result of IB’s limited voting power and Wolverine’s lack of board representation, the voting power of the respective BOX Holdings directors designated by each of the other BOX Holdings Members is greater than the respective BOX Holdings Member’s voting power with respect to BOX Holdings Member matters. The BOX Holdings board voting power of directors designated by each of the BOX Holdings Members greater than 10% is as follows: MXUS2: 45.50%; IB: 20.00% and Citadel: 14.73%.

Medici Ventures, L.P. (“Medici”), a Delaware limited partnership, owns 44% of the outstanding shares of tZERO, Overstock.com, Inc. (“Overstock”), a publicly held corporation organized under the laws of the state of Delaware, owns 43% of the outstanding shares of tZERO, Joseph Cammarata holds 7.53% of the outstanding shares of tZERO, and each of the following owns less than 3% of the outstanding shares of tZERO: Todd Tobacco, Newer Ventures LLC, Schalk Steyn, Raj Karkara, Alec Wilkins, Dohi Ang, Brian Capuano, Trent Larson,

¹⁸ “Units” mean Class A Units and Class B Units. For the avoidance of doubt, the ownership or possession of Units shall not in and of itself entitle the owner or holder thereof to vote or consent to any action with respect to the Company (which rights shall be vested only in duly admitted Members of the Company), or to exercise any right of a Member of the Company under the LLC Agreement, the LLC Act, or other applicable law. See Section 1.1, LLC Agreement. References herein to “Units” refer to Class A and Class B Units of the Company unless a separate class is specified.

¹⁹ “Class A Units” shall mean equal units of limited liability company interest in the Company, including an interest in the ownership and profits and losses of the Company and the right to receive distributions from the Company as set forth in the LLC Agreement. See Section 1.1, LLC Agreement.

²⁰ “Class B Units” shall be identical to Class A Units except that Class B Members shall not have the right to vote on any matter related to the Company as a result of holding Class B Units. See Section 1.1, LLC Agreement.

²¹ Pursuant to Section 2.5(b) of the LLC Agreement, upon the consummation of any sale or transfer of a majority of the Class A Units or a majority of the assets of the Company, directly or indirectly, to any party or group of related parties, including through a series of transactions, all then outstanding Class B Units shall automatically convert into an equal number of Class A units without the need of any action by any person. For the avoidance of doubt, a Class B Member’s Capital Account does not change as a result of the conversion of the Class B Units.

²² Three current Directors hold non-voting Class B Units; specifically, these Directors are Members and hold, directly or indirectly, the following economic interest percentages in the Company: Alan Konevsky 0.36%, Will Easley 0.36%, and Lisa Fall 4.98%. Ms. Fall is CEO of BSTX and BOX Digital.

²³ The Membership Record shall include the name and address of each Member and the number of Units of each class held by each Member.

²⁴ See BOX Holdings LLC Agreement Sections 1.1 and 2.5.

²⁵ Class B Units of BOX Holdings are identical to Class A Units except Class B Units include conversion rights, a liquidation preference and class voting rights with respect to those matters. See BOX Holdings LLC Agreement §§ 1.1 and 2.5.

²⁶ See BOX Holdings LLC Agreement Section 1.1.

²⁷ See BOX Holdings LLC Agreement Section 7.4(h).

²⁸ See BOX Holdings LLC Agreement Section 4.3(b).

Eric Fish, Kristen Anne Bagley, Kirstie Dougherty, SpeedRoute Technologies Inc., Tommy McSherry, Rob Collucci, John Gilchrist, John Paul DeVito, Jimmy Ambrose, Jason Heckler, Max Melmed, Alex Vlastakis, Olalekan Abebefe, Samson Arubuola, Ryan Mitchell, Zachary Wilezol, Anthony Bove, Ralph Daiuto, Rob Christiansen, Amanda Gervase, Derek Tobacco, Steve Bailey, and Dinosaur Financial. Pelion MV GP, L.L.C. ("Medici GP"), a Delaware limited liability company, serves as the general partner of Medici and has the sole right to manage its affairs. Medici GP owns 1% of the partnership interests in Medici (along with a profits interest in Medici), and Overstock owns 99% of the partnership interests in Medici. Membership interests in Medici GP are held by the following, each of which holds less than 25% of Medici GP: Carine Clark, Susannah Duke, Steve Glover, Brad Hintze, Jeff Kearn, Trevor Lund, Matt Mosman, Erika Nash, Zain Rizavi, Laura Summerhays, The Blake G Modersitzki 2020 Irrevocable Trust (affiliated with Blake G. Modersitzki), The Capitola Trust (affiliated with Chad Packard), The GP Investment Trust (affiliated with Chris Cooper) and The Oaxaca Dynasty Trust (affiliated with Ben Lambert). Therefore, both tZERO and the Company are affiliates of Overstock, Medici and Medici GP.

Pursuant to Section 7.4(g)(ii) of the LLC Agreement, any Controlling Person²⁹ is required to become a party

²⁹ A "Controlling Person" is defined as "a Person who, alone or together with any Related Persons of such Person, holds a Controlling Interest in a Member." See Section 7.4(g)(v)(B), LLC Agreement. A "Controlling Interest" is defined as "the direct or indirect ownership of 25% or more of the total voting power of all equity securities of a Member (other than voting rights solely with respect to matters affecting the rights, preferences, or privileges of a particular class of equity securities), by any Person, alone or together with any Related Persons of such Person." See Section 7.4(g)(v)(A), LLC Agreement. A "Related Person" is defined as "with respect to any Person: (A) Any Affiliate of such Person; (B) any other Person with which such first Person has any agreement, arrangement or understanding (whether or not in writing) to act together for the purpose of acquiring, voting, holding or disposing of Units; (C) in the case of a Person that is a company, corporation or similar entity, any executive officer (as defined under Rule 3b-7 under the [Act]) or director of such Person and, in the case of a Person that is a partnership or limited liability company, any general partner, managing member or manager of such Person, as applicable; (D) in the case of any BSTX Participant who is at the same time a broker-dealer, any Person that is associated with the BSTX Participant (as determined using the definition of "person associated with a member" as defined under Section 3(a)(21) of the [Act]); (E) in the case of a Person that is a natural person and a BSTX Participant, any broker or dealer that is also a BSTX Participant with which such Person is associated; (F) in the case of a Person that is a natural person, any relative or spouse of such Person, or any relative of such spouse who has the same home as

to the LLC Agreement and abide by its provisions, to the same extent and as if they were Members. This provision and the associated definitions of Controlling Person and Controlling Interest are the same as currently apply to BOX Holdings.³⁰ Accordingly, prior to commencing operations as a facility of the Exchange, BSTX will obtain, from each Controlling Person, an instrument of accession substantially in the form attached hereto as Exhibit 5B [sic]. Related Persons that are otherwise Controlling Persons are not required to become parties to the LLC Agreement if they are only under common control of an upstream owner but are not in the upstream ownership chain above a Company owner because they will not have the ability to exert any control over the Company. BOX Holdings, Medici, Medici GP and Overstock are indirect owners of the Company. Medici GP owns 1% of the partnership interests and a profits interest in Medici and acts as Medici's general partner. Overstock owns 43% of tZERO directly and 99% of Medici, which owns 44% of tZERO. As a result, Overstock owns, directly or indirectly, more than 80% of tZERO, which owns 50% of the voting class of equity of BSTX. Overstock, Medici and Medici GP will be required to become parties to the Company's LLC Agreement by executing an instrument of accession and abide by its provisions, to the same extent and as if they were Members, because they are Controlling Persons of the Company. Similarly, BOX Digital, BOX Holdings, MXUS2, MX US 1, Inc., Bourse de Montreal Inc., and TMX Group Limited will also each be required to become parties to the LLC Agreement by executing an instrument of accession and abide by its provisions to the same extent and as if they were Members because they are Controlling Persons of the Company. TMX Group Limited owns 100% of Bourse de Montreal Inc., which owns 100% of MX US 1, Inc., which owns 100% of MXUS2, which owns more than 40% of

such Person or who is a director or officer of the Exchange or any of its parents or subsidiaries; (G) in the case of a Person that is an executive officer (as defined under Rule 3b-7 under the [Act]) or a director of a company, corporation or similar entity, such company, corporation or entity, as applicable; and (H) in the case of a Person that is a general partner, managing member or manager of a partnership or limited liability company, such partnership or limited liability company, as applicable." A "Person" is defined as "any individual, partnership, corporation, association, trust, limited liability company, joint venture, unincorporated organization and any government, governmental department or agency or political subdivision thereof." See Section 1.1, LLC Agreement.

³⁰ See Section 7.4(g), BOX Holdings LLC Agreement.

BOX Holdings. Each of these upstream owners of BOX Holdings is a Controlling Person required to be, and is, a party to, and be subject to, the BOX Holdings LLC Agreement. BOX Holdings owns 98% of BOX Digital, which owns 50% of the voting class of equity of BSTX.

Pursuant to Section 7.4(h) of the LLC Agreement,³¹ in the event any Member, or any Related Person of such Member, is approved by the Exchange as a BSTX Participant pursuant to the Exchange Rules, and such Member owns more than 20% of the Units, alone or together with any Related Person of such Member (Units owned in excess of 20% being referred to as "Excess Units"), the Member and its appointed Member Directors shall have no voting rights whatsoever with respect to any action relating to the Company nor shall the Member or its appointed Member Directors, if any, be entitled to give any proxy in relation to a vote of the Members, in each case solely with respect to the Excess Units held by such Member; provided, however, that whether or not such Member or its appointed Member Directors, if any, otherwise participates in a meeting in person or by proxy, such Member's Excess Units shall be counted for quorum purposes and shall be voted by the person presiding over quorum and vote matters in the same proportion as the Units held by the other Members are voted (including any abstentions from voting). In addition, an effective rule filing pursuant to Section 19 of the Act shall be required prior to any Member, or any Related Person of such Member, becoming a BSTX Participant if such Member, alone or together with any Related Persons of such Member, has the right to appoint more than 20% of the Directors entitled to vote and, unless a rule filing authorizing the foregoing is first effective, such Member, or any Related Person of such Member, shall not be registered as a BSTX Participant. These limitations are designed to prevent a market participant from exerting undue influence on a facility of the Exchange. Related Persons will be grouped together when applying these limits. Accordingly, any Related Persons of tZERO or another Member will not be a BSTX Participant without completing the rule filing process. The Exchange believes the proposed voting cap provision is consistent with the Act, including Section 6(b)(1), which requires, in part, an exchange to be so organized and have the capacity to carry

³¹ LLC Agreement Section 7.4(h) is based on Section 7.4(h) of the BOX Holdings LLC Agreement.

out the purposes of the Act.³² In particular, the voting cap is designed to minimize the ability of a BSTX Participant to improperly interfere with or restrict the ability of the Exchange to effectively carry out its regulatory oversight responsibilities under the Act.

Any Member shall provide the Company with written notice fourteen (14) days prior, and the Company shall provide the SEC and the Exchange with written notice ten (10) days prior, to the closing date of any acquisition that results in such Member's Percentage Interest,³³ alone or together with any Related Person of such Member, meeting or crossing the threshold level of 5% or the successive 5% Percentage Interest levels of 10% and 15%.³⁴ Further, rule filings are required for any Transfer³⁵ that results in the acquisition and holding by any Person, alone or together with its Related Persons, of an aggregate Percentage Interest level which meets or crosses the threshold level of 20% or any successive 5% Percentage Interest level (*i.e.*, 25%, 30%, etc.).³⁶ These are the same provisions as are contained in the BOX Holdings LLC Agreement. The Exchange believes the proposed notification provisions are consistent with the Act, including Section 6(b)(1), which requires, in part, an exchange to be so organized and have the capacity to carry out the purposes of the Act.³⁷ In particular, SEC notification of ownership interests exceeding certain percentage thresholds can help improve the Commission's ability to effectively monitor and surveil for potential undue influence and control over the operation of the Exchange.

The Exchange is the entity that will have regulatory oversight of BSTX. All

owners of the Exchange are limited to 40% economic ownership and 20% voting power on the Exchange.³⁸ In addition, owners of the Exchange that are also Exchange Facility Participants are further limited to a maximum of 20% economic ownership of the Exchange and are still subject to the general limitation of 20% voting power of the Exchange.³⁹ The Exchange notes these existing ownership limits applicable to owners of the Exchange are not changing.⁴⁰ The Exchange believes these existing ownership limits will help to ensure the independence of the Exchange's regulatory oversight of BSTX and facilitate the ability of the Exchange to carry out its regulatory responsibilities and operate in a manner consistent with the Act, and are appropriate and consistent with the requirements of the Act, particularly with Section 6(b)(1), which requires, in part, an exchange be so organized and have the capacity to carry out the purposes of the Act.⁴¹

The Company does not have the same ownership as BOX Options or BOX Holdings; therefore, the Members of the Company differ from those of BOX Options and BOX Holdings. The Exchange believes that the structure of the Company will promote just and equitable principles of trade, and, in general, protect investors and the public interest, consistent with Section 6(b)(5) of the Act.⁴²

Term and Termination

In the discussion below, the Exchange describes provisions in the LLC Agreement related to the term and termination of the Company, highlighting areas that vary in comparison to the BOX Options LLC Agreement and/or BOX Holdings LLC Agreement and provides the statutory basis for such variation.

Pursuant to Section 2.3 of the LLC Agreement, the Company will have a perpetual legal existence unless it is sooner dissolved as a result of an event specified in the Delaware Limited Liability Company Act, as amended and in effect from time to time, and any successor statute (the "LLC Act") or by agreement of the Members. The term is the same as the provision in the BOX Options LLC Agreement,⁴³ but also provides that the Company can be dissolved by agreement of the Members.

In addition, Section 10.1 of the LLC Agreement provides that the Company shall be dissolved upon (i) the election to dissolve the Company made by the Board pursuant to Section 4.4(b)(v) of the LLC Agreement; (ii) the entry of a decree of judicial dissolution under § 18–802 of the LLC Act; (iii) the resignation, expulsion, bankruptcy or dissolution of the last remaining Member, or the occurrence of any other event which terminates the continued membership of the last remaining Member in the Company, unless the business of the Company is continued without dissolution in accordance with the LLC Act; or (iv) the occurrence of any other event that causes the dissolution of a limited liability company under the LLC Act unless the Company is continued without dissolution in accordance with the LLC Act. The dissolution events are generally the same as those in the BOX Options LLC Agreement;⁴⁴ however, the Company may also be dissolved by the affirmative vote of Members holding a majority of all of the then outstanding Percentage Interests (excluding any Percentage Interests held directly or indirectly by tZERO and its Affiliates⁴⁵ from the numerator and the denominator for such calculation) taken within 180 calendar days after the occurrence of any "Trigger Event" as such term is defined in the IP License and Services Agreement entered into by and between tZERO and the Company (the "LSA") and described in more detail below.⁴⁶ The Exchange believes

⁴⁴ See BOX Options LLC Agreement Section 8.1.

⁴⁵ An "Affiliate" is defined as "with respect to any Person, any other Person controlling, controlled by or under common control with, such Person. As used in this definition, the term "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise with respect to such Person. A Person is presumed to control any other Person, if that Person: (i) is a director, general partner, or officer exercising executive responsibility (or having similar status or performing similar functions); (ii) directly or indirectly has the right to vote 25 percent or more of a class of voting security or has the power to sell or direct the sale of 25 percent or more of a class of voting securities of the Person; or (iii) in the case of a partnership, has contributed, or has the right to receive upon dissolution, 25 percent or more of the capital of the partnership." See Section 1.1, LLC Agreement.

⁴⁶ The LSA defines a "Trigger Event" as meaning "any of the following events: (a) A material breach by tZERO of any of its obligations under this LSA (being either a single event which is a material breach or a series of breaches which taken together are a material breach) which material breach or failure is not cured by tZERO within 90 days after Company gives written notice of such breach or failure to tZERO hereunder, except for system availability issues in which case the cure period shall be 10 days; (b) any bankruptcy, reorganization,

Continued

³² 15 U.S.C. 78f(b)(1).

³³ "Percentage Interest" means "with respect to a Member, the ratio of the number of Unit held by the Member to the total of all of the issued Units, expressed as a percentage and determined with respect to each class of Units whenever applicable." See Section 1.1, LLC Agreement.

³⁴ See LLC Agreement, Section 7.4(e). LLC Agreement Section 7.4(e) is based on Section 7.4(e) of the BOX Holdings LLC Agreement.

³⁵ "Transfer" means the actions of a Person to "directly or indirectly, whether voluntarily, involuntarily, by operation of law or otherwise, dispose of, sell, alienate, assign, exchange, participate, subparticipate, encumber, or otherwise transfer in any manner" its Units but does not include "transfers among Members, transfers to any Person directly or indirectly owning, controlling or holding with power to vote all of the outstanding voting securities of and equity or beneficial interests in that Member, or transfers to any Person that is a wholly owned Affiliate of a transferring Member." See LLC Agreement, Section 7.1(a).

³⁶ See LLC Agreement, Section 7.4(f). LLC Agreement Section 7.4(f) is based on Section 7.4(f) of the BOX Holdings LLC Agreement.

³⁷ 15 U.S.C. 78f(b)(1).

³⁸ See Exchange LLC Agreement Section 7.3.

³⁹ See Exchange LLC Agreement Section 7.3.

⁴⁰ See Securities Exchange Act Release No. 34–66871 (April 27, 2012) 77 FR 26323 (May 3, 2012) (Order granting approval of BOX Exchange).

⁴¹ 15 U.S.C. 78f(b)(1).

⁴² 15 U.S.C. 78f(b)(5).

⁴³ See BOX Options LLC Agreement Section 2.3.

that the addition of such dissolution events will promote just and equitable principles of trade, and, in general, protect investors and the public interest, consistent with Section 6(b)(5) of the Act.⁴⁷

Upon the occurrence of any of the events set forth in Section 10.1(a) of the LLC Agreement, the Company will be dissolved and terminated in accordance with the provisions of Article 10 of the LLC Agreement.

Governance of the Company

In the discussion below, the Exchange describes provisions in the LLC Agreement related to the governance of the Company, highlighting areas that vary in comparison to the BOX Options LLC Agreement and/or BOX Holdings LLC Agreement and provides the statutory basis for such variation.

Section 4.1 of the LLC Agreement establishes a board of directors of the Company (the "Board of Directors" or the "Board") to manage the development, operations, business and affairs of the Company without the need for any approval of the Members or any other person. Section 4.10 of the LLC Agreement provides that, except and only to the extent expressly provided for in the LLC Agreement and the Related Agreements and as delegated by the Board of Directors to committees of the Board of Directors or to duly appointed Officers or agents of the Company, neither a Member nor any other Person other than the Board of Directors shall be an agent of the Company or have any right, power or authority to transact any business in the name of the Company or to act for or on behalf of or to bind the Company. Section 4.12(a) of the LLC Agreement provides that each of the Members and the Directors, Officers, employees and agents of the Company (a) shall give due regard to the preservation of the independence of the self-regulatory function of the Exchange and to its obligations to investors and the general public and shall not take any actions which would interfere with the effectuation of decisions by the board of directors of the Exchange relating to its

regulatory functions (including disciplinary matters) or which would interfere with the Exchange's ability to carry out its responsibilities under the Act; (b) comply with the federal securities laws and the rules and regulations promulgated thereunder; and (c) cooperate with the Exchange pursuant to its regulatory authority and with the SEC. Section 3.2 of the LLC Agreement provides that the Exchange will (a) act as the SEC-approved SRO for the BSTX Market, (b) have regulatory responsibility for the activities of the BSTX Market and provide regulatory services to the Company pursuant to the Facility Agreement. These are the same provisions that are contained in the BOX Options LLC Agreement.⁴⁸ These provisions ensure that the Exchange has full regulatory control over BSTX, which is designed to prevent any owner of BSTX from exercising undue influence over the regulated activities of the Company.

Section 4.1 of the LLC Agreement provides that the Board will consist of six (6) directors (each a "Director"), comprised of two (2) Directors appointed by BOX Digital, two (2) Directors appointed by tZERO (together with the BOX Digital Directors, each a "Member Director"), one (1) Director (the "Independent Director") appointed by the unanimous vote of all of the then serving Member Directors, and one (1) non-voting Director (the "Regulatory Director") appointed by the Exchange. As long as the Company is a facility of the Exchange pursuant to Section 3(a)(2) of the Act, the Exchange will have the right to appoint a Regulatory Director to serve as a Director. The Regulatory Director must be a member of the senior management of the regulation staff of the Exchange. By comparison, the board of directors of BOX Options is the same as BOX Holdings because it is a wholly-owned subsidiary of BOX Holdings. The remaining structure of the Board of Directors for the Company differs from that of BOX Holdings because the ownership of the Company differs from that of BOX Holdings, which has more than two owners of its voting class of equity, as discussed above. By comparison, the BOX Holdings board of directors uses a tiered system in which board voting is based on ownership percentage of the BOX Holdings owner that appointed each director. Specifically, in the BOX Holdings system, each owner of BOX Holdings is entitled to appoint a number of directors based on the percentage of total outstanding units of BOX Holdings held

by such owner⁴⁹ and all of the BOX Holdings directors appointed by a single owner of BOX Holdings, together, possess voting power on the BOX Holdings board of directors commensurate with the percentage of outstanding units of BOX Holdings held by the owner appointing such directors.⁵⁰ The Exchange believes the organization of the BSTX Board is simple and effective in limiting any one Member to be able to control a maximum of 40% of voting power of the full Board. Further, the Exchange believes the organization of the BSTX Board is consistent with Section 6(b)(1) of the Act by helping to ensure the Exchange, including in the operation of any facilities, continues to be so organized and has the capacity to carry out the purposes of the Act. The Company has an Independent Director to avoid either Member from controlling or creating deadlock on the Board. However, the presence of a Regulatory Director selected by the Exchange on the Board is identical to the longstanding practice at the Exchange's other facility, BOX Options. The Exchange believes that the proposed board structure, and in particular, the inclusion of the proposed Independent Director and Regulatory Director, will promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, consistent with Section 6(b)(5) of the Act.⁵¹ Further, the Exchange believes that inclusion of the Regulatory Director on the BSTX Board would also be consistent with Section 6(b)(1) of the Act. This is because the Regulatory Director is required to be someone who is a member of the senior management of the regulation staff of the Exchange and is therefore a person who is knowledgeable of the rules of the Exchange and the regulations applicable to it and, in turn, is someone who would be well positioned to help ensure the Exchange, including in the operation of any facilities, continues to be so organized and has the capacity to carry out the purposes of the Act,

debt arrangement, or other case or proceeding under any bankruptcy or insolvency Law or any non-frivolous dissolution or liquidation proceedings commenced by or against tZERO; and if such case or proceeding is not commenced by tZERO, it is acquired by tZERO in or remains undismissed for 30 days; (c) tZERO ceasing active operation of its business without a successor or discontinuing any of the Base Services; (d) tZERO becomes judicially declared insolvent or admits in writing its inability to pay its debts as they become due; or (e) tZERO applies for or consents to the appointment of a trustee, receiver or other custodian for tZERO, or makes a general assignment for the benefit of its creditors."

⁴⁷ 15 U.S.C. 78f(b)(5).

⁴⁸ See BOX Options LLC Agreement Sections 4.1, 4.10, 4.12, and 3.2.

⁴⁹ See Section 4.1(a), BOX Holdings LLC Agreement.

⁵⁰ See Section 4.3(b), BOX Holdings LLC Agreement.

⁵¹ 15 U.S.C. 78f(b)(5).

including to prevent inequitable and unfair practices.

Section 4.3 of the LLC Agreement provides that the Board will meet as often as it deems necessary, but at least four (4) times per year.⁵² Meetings of the Board or any committee thereof may be conducted in person or by telephone or in any other manner agreed to by the Board or, respectively, by the members of a committee. Any of the Directors or the Exchange may call a meeting of the Board upon fourteen (14) calendar days prior written notice. In any case where the convening of a meeting of Directors is a matter of urgency, notice of the meeting may be given not less than forty-eight (48) hours before the meeting is to be held. No notice of a meeting shall be necessary when all Directors are present. The attendance of at least a majority of all the Directors shall constitute a quorum for purposes of any meeting of the Board. Except as may otherwise be provided by the LLC Agreement, each of the Directors will be entitled to one vote on any action to be taken by the Board, except that the Regulatory Director shall not vote on any action to be taken by the Board or any committee, the CEO (if a Director) shall not be entitled to vote on matters relating to the CEO's powers, compensation or performance, and a Director shall not be entitled to vote on any matter pertaining to that Director's removal from office. A Director may vote the votes allocated to another Director (or group of Directors) pursuant to a written proxy. Except as otherwise provided by the LLC Agreement, any action to be taken by the Board shall be considered effective only if approved by at least a majority of the votes entitled to be voted on that action. Meetings of the Board may be attended by other representatives of the Members, the Exchange and other persons related to the Company as the Board may approve.⁵³ Any action required or permitted to be taken at a meeting of the Board or any committee thereof may be taken without a meeting if written consents, setting forth the action so taken, are executed by the members of

the Board or committee, as the case may be, representing the minimum number of votes that would be necessary to authorize or to take that action at a meeting at which all members of the Board or committee, as the case may be, permitted to vote were present and voted. The Board will determine procedures relating to the recording of minutes of its meetings. The Exchange believes that the proposed board structure will promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, consistent with Section 6(b)(5) of the Act.⁵⁴

Pursuant to Section 4.4 of the LLC Agreement, no action with respect to any major action (each a "Major Action"), will be effective unless approved by the Board, including the affirmative vote of all then serving Member Directors, in each case acting at a meeting. A vacancy on the Board will not prevent approval of a Major Action. No other Member votes are required for a Major Action. For purposes of the LLC Agreement, "Major Action" means any of the following: (i) A merger or consolidation of the Company with any other entity or the sale by the Company of any material portion of its assets; (ii) entry by the Company into any line of business other than the business outlined in Article 3 of the LLC Agreement; (iii) conversion of the Company from a Delaware limited liability company into any other type of entity; (iv) except as expressly contemplated by the LLC Agreement and then existing Related Agreements, entering into any agreement, commitment, or transaction with any Member or any of its Affiliates other than transactions or agreements upon commercially reasonable terms that are no less favorable to the Company than the Company would obtain in a comparable arms-length transaction or agreement with a third party; (v) to the fullest extent permitted by law, taking any action (except pursuant to a vote of the Members pursuant to Section 10.1(a)(iii)) of the LLC Agreement to effect the voluntary, or which would precipitate an involuntary, dissolution or winding up of the Company; (vi) operating the BSTX Market utilizing any other software system, other than the

BSTX System, except as otherwise provided in the LSA or to the extent otherwise required by the Exchange to fulfill its regulatory functions or responsibilities or to oversee the BSTX Market as determined by the board of the Exchange; (vii) operating the BSTX Market utilizing any other regulatory services provider other than the Exchange, except as otherwise provided in the Facility Agreement or to the extent otherwise required by the Exchange to fulfill its regulatory functions or responsibilities or to oversee the BSTX Market as determined by the board of the Exchange; (viii) entering into any partnership, joint venture or other similar joint business undertaking; (ix) making any fundamental change in the market structure of the Company from that contemplated by the Members as of the date of the LLC Agreement, except to the extent otherwise required by the Exchange to fulfill its regulatory functions or responsibilities or to oversee the BSTX Market as determined by the board of the Exchange; (x) issuing any new Units pursuant to Section 7.6 of the LLC Agreement or admitting additional or substitute Members pursuant to Section 7.1(b); (xi) altering the provisions for Board membership applicable to any Member, except to the extent otherwise required by the Exchange to fulfill its regulatory functions or responsibilities or to oversee the BSTX Market as determined by the board of the Exchange; and (xii) altering the definition of or requirements for approving a Major Action, except to the extent otherwise required by the Exchange to fulfill its regulatory functions or responsibilities or to oversee the BSTX Market as determined by the board of the Exchange. The Major Action events are generally the same as those in the BOX Options LLC Agreement and BOX Holdings LLC Agreement⁵⁵ with the exception of deletions to references to BOX Options affiliates and owners and to include cross references to other provisions of the LLC Agreement; however, the Company's LLC Agreement also provides that a Major Action also includes provisions (viii), (x), and (xi) as described above. The Exchange believes that such events should be deemed Major Actions for commercial fairness. The Exchange believes that deeming the above referenced events as Major Actions will promote just and equitable principles of trade, foster cooperation and

⁵² LLC Agreement Section 4.3 is based on Section 4.3 of the BOX Options LLC Agreement.

⁵³ Section 4.3 of the BOX Options LLC Agreement varies from Section 4.3 of the LLC Agreement in that the corresponding sentence in Section 4.3 of the BOX Options LLC Agreement references BOX Holdings Members rather than Members of the existing facility, BOX Options, while Section 4.3 of the LLC Agreement references Members of the proposed facility, BSTX. This difference is because BOX Options is wholly-owned by BOX Holdings and, therefore, BOX Options has only one owner. Accordingly, ownership of the existing facility, BOX Options, diverges with the Members of BOX Holdings while ownership of the proposed facility, BSTX, diverges with the Members of BSTX.

⁵⁴ 15 U.S.C. 78f(b)(5).

⁵⁵ See Section 4.4 of the BOX Options LLC Agreement and Section 4.4 of the BOX Holdings LLC Agreement.

coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, consistent with Section 6(b)(5) of the Act.⁵⁶ In addition, such requirements enhance the ability of the Exchange and its proposed facility, BSTX, to effectively carry out its regulatory responsibilities under the Act, particularly with Section 6(b)(1) thereof, which requires, in part, an exchange be so organized and have the capacity to carry out the purposes of the Act.

Pursuant to Section 4.1(b) of the LLC Agreement, a Member Director may be removed by the Member entitled to appoint that Member Director, with or without cause. The Independent Director may be removed by a majority vote of the then serving Member Directors, with or without cause. Any Member Director or Independent Director may be removed by the Board if the Board determines, in good faith, that the Director has violated any provision of the LLC Agreement or any federal or state securities law or that such action is necessary or appropriate in the public interest or for the protection of investors. A Director shall not participate in any vote regarding that Director's removal. The Company shall promptly notify the Exchange in writing of the commencement or cessation of service of a Member Director or Independent Director. Like BOX Options, Directors may be removed by the Board for reasons related to protection of investors and the owners with rights to appoint a Member Director have power to remove and replace their respective designees. The removal provisions for the Company's Independent Director differ from those of BOX Options and BOX Holdings because those entities do not have an Independent Director. The Exchange believes that the proposed removal provisions will promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, consistent with Section 6(b)(5) of the Act. Further, the Exchange believes that

the ability for Member Directors and Independent Directors to be removed from the Board in the circumstances described above would be consistent with Section 6(b)(1) of the Act.⁵⁷ This is because removal of such Directors who have violated the LLC Agreement or federal or state laws would help ensure that the Exchange, including in its operation of facilities, is so organized and has the capacity to be able to carry out the purposes of the Act, including the prevention of inequitable and unfair practices.

Section 4.1(c) of the LLC Agreement provides that, if a vacancy is created on the Board as a result of the death, disability, retirement, resignation or removal (with or without cause) of a Member Director or otherwise there shall exist or occur any vacancy on the Board, the Member whose designee created the vacancy will fill that vacancy by written notice to the Company. Each Member shall promptly fill vacancies on the Board, and the Board shall consider the advisability of taking further action until the vacancies are filled. The vacancy provisions are not in the BOX Options LLC Agreement; however, the Exchange believes that providing for contingencies in the event of a vacancy are important to avoid business disruption and, therefore, this proposal will foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, consistent with Section 6(b)(5) of the Act.⁵⁸ Further, the Exchange believes that filling Director vacancies, as described above, would provide a predetermined and transparent manner for filling Director vacancies and therefore help avoid business disruptions at BSTX. The Exchange believes that this, in turn, would be consistent with Section 6(b)(1) of the Act⁵⁹ because it would help ensure that the Exchange, including in the operation of facilities, is so organized and has the capacity to be able carry out the purposes of the Act, including to remove impediments to and perfect the mechanisms of a national market system for securities.

Section 4.1(d) of the LLC Agreement provides that the Regulatory Director may be removed (a) by the Exchange, with or without cause, (b) by the Board if the Board determines, in good faith, that the Regulatory Director has violated any provision of the LLC Agreement or any federal or state securities law, or (c)

by the Board if the Board determines, in good faith, that the Regulatory Director does not meet the requirements of a Regulatory Director as set forth in the LLC Agreement. If the Regulatory Director ceases to serve for any reason, the Exchange shall appoint a new Regulatory Director in accordance with the requirements in the LLC Agreement. The removal provisions in the Company's LLC Agreement are substantially the same as those in the BOX Options LLC Agreement.⁶⁰

Section 4.12(b) of the LLC Agreement provides that the Company and its Members shall comply with the federal securities laws and the rules and regulations promulgated thereunder and shall cooperate with the SEC and the Exchange pursuant to and to the extent of their respective regulatory authority. The Directors, Officers, employees and agents of the Company, by virtue of their acceptance of such position, shall comply with the federal securities laws and the rules and regulations promulgated thereunder and shall be deemed to agree to cooperate with the SEC and the Exchange in respect of the SEC's oversight responsibilities regarding the Exchange, and the Company shall take reasonable steps necessary to cause its Directors, Officers, employees and agents to so cooperate. These provisions in the LLC Agreement are the same as those in the BOX Options LLC Agreement and BOX Holdings LLC Agreement.⁶¹

Section 3.2(a)(ii) of the LLC Agreement provides that the Exchange shall receive notice of planned or proposed changes to the Company (but not including changes relating solely to one or more of the following: marketing, administrative matters, personnel matters, social or team building events, meetings of the Members, communication with the Members, finance, location and timing of Board meetings, market research, real property, equipment, furnishings, personal property, intellectual property, insurance, contracts unrelated to the operation of the BSTX Market and de minimis items ("Non-Market Matters")) or the BSTX Market (including, but not limited to the BSTX System) which will require an affirmative approval by the Exchange prior to implementation, not inconsistent with the LLC Agreement. Planned changes include, without limitation: (a) Planned or proposed changes to the BSTX System means the

⁶⁰ See Section 4.1(d) of the BOX Options LLC Agreement.

⁶¹ See Section 4.12(b) of the BOX Options LLC Agreement and Section 4.12(b) of the BOX Holdings LLC Agreement.

⁵⁶ 15 U.S.C. 78f(b)(5).

⁵⁷ 15 U.S.C. 78f(b)(1).

⁵⁸ 15 U.S.C. 78f(b)(5).

⁵⁹ 15 U.S.C. 78f(b)(1).

technology, know-how, software, equipment, communication lines or services, services and other deliverables or materials of any kind as may be necessary or desirable for the operation of the BSTX Market; (b) the sale by the Company of any material portion of its assets; (c) taking any action to effect a voluntary, or which would precipitate an involuntary, dissolution or winding up of the Company; or (d) obtaining regulatory services from a regulatory services provider other than the Exchange. Procedures for requesting and approving changes shall be established by the mutual agreement of the Company and the Exchange.⁶² These provisions in the LLC Agreement are the same as those in the BOX Options LLC Agreement.⁶³

Section 3.2(a)(iii) of the LLC Agreement provides that in the event that the Exchange, in its sole discretion, determines that the proposed or planned changes to the Company or the BSTX Market (including, but not limited to, the BSTX System) set forth in Section 3.2(a)(ii) of the LLC Agreement could cause a Regulatory Deficiency⁶⁴ if implemented, the Exchange may direct the Company, subject to approval of the Exchange board of directors, to modify the proposal as necessary to ensure that it does not cause a Regulatory Deficiency. The Company will not implement the proposed change until it, and any required modifications, are approved by the Exchange board of directors. The costs of modifications undertaken shall be paid by the Company. These provisions in the LLC Agreement are the same as those in the BOX Options LLC Agreement.⁶⁵ These provisions ensure the Exchange maintains full regulatory control and authority over BSTX while it operates as

a facility of the Exchange. The Exchange believes this provision helps guarantee the Exchange's ability to fulfill its regulatory responsibilities and operate in a manner consistent with the Act, in particular with Section 6(b)(1), which requires, in part, an exchange to be so organized and have the capacity to carry out the purposes of the Act.⁶⁶

Section 3.2(a)(iv) of the LLC Agreement provides that in the event that the Exchange, in its sole discretion, determines that a Regulatory Deficiency exists or is planned, the Exchange may direct the Company, subject to approval of the Exchange board of directors, to undertake such modifications to the Company (but not to include Non-Market Matters) or the BSTX Market (including, but not limited to, the BSTX System), as are necessary or appropriate to eliminate or prevent the Regulatory Deficiency and allow the Exchange to perform and fulfill its regulatory responsibilities under the Act.⁶⁷ The costs and modifications undertaken shall be paid by the Company. These provisions in the LLC Agreement are substantially the same as those in the BOX Options LLC Agreement, with the exception of a reference to an agreement that is not applicable to the Company.⁶⁸

Section 3.2(c) of the LLC Agreement states that BOX Digital will provide executive leadership and exclusive rights to the regulatory services of the Exchange with respect to BSTX Products. With the consent of the Exchange, BOX Digital holds exclusive rights to the regulatory services of the Exchange with respect to BSTX Products. BOX Digital directors, officers and employees, including its CEO, Lisa Fall, are experienced executive managers of SROs and exchange facilities. In becoming a Member of BSTX and becoming a party to the LLC Agreement, BOX Digital agreed to contribute these assets to the Company.

Regulatory Funds

The Exchange represents that the Facility Agreement will require the

Company to provide adequate funding for the Exchange's operations with respect to the Company, including the regulation of the Exchange. The Facility Agreement will provide that the Exchange receives all fees, including regulatory fees and trading fees, payable by BSTX Participants, as well as any funds received from any applicable market data fees, tape and other revenue. The Exchange represents that fees received from all Exchange facilities, including fees from BSTX Participants, will be adequate to operate the Exchange and to regulate the Company. The Facility Agreement will further provide that the Company will reimburse the Exchange for its costs and expenses to the extent the Exchange's assets are insufficient. The Exchange will require the Company to allocate sufficient available funds to adequately operate the facility until it begins receiving revenues from operations. Prior to commencing operations as a facility of the Exchange, the Company will have all such necessary funds and assets, including furnishings, equipment and servers. To the extent the Company needs any additional funding to meet this requirement, such funds will be provided to the Company by one or more of its Members.

Pursuant to Section 9 of the Facility Agreement, the Company will agree that the Exchange has the right to receive all fees, fines and disgorgements imposed upon BSTX Participants with respect to the Company's trading system ("Regulatory Funds") and all market data fees, tape and other revenues ("Non-regulatory Funds"). All Regulatory Funds and Non-regulatory Funds collected by the Exchange with respect to the Company may be used by the Exchange for regulatory purposes, which will be determined in the sole discretion of the Exchange. In determining the excess funds to remit to the Company, the Exchange will exercise prudent financial management (including cash flow management) and may retain funds for anticipated and unanticipated expenses. To the extent the Company incurs costs and expenses for regulatory purposes, the Exchange may reimburse the Company using Regulatory Funds. In the event the Exchange, at any time, determines that it does not hold sufficient funds to meet all regulatory purposes, the Company will reimburse the Exchange for any such additional costs and expenses. All Regulatory Funds collected by the Exchange will be retained by the Exchange and not transferred to the Company. Non-regulatory funds collected by the Exchange may be

⁶² The language providing that procedures for requesting and approving changes shall be established by the mutual agreement of the Company and the Exchange does not diminish the power and authority of the Exchange to regulate such changes because, if the Company and the Exchange cannot agree on procedure, the Exchange simply will not approve any such change. By the terms of Section 3.2(a)(ii) of the LLC Agreement, planned or proposed changes to the Company will require an affirmative approval by the Exchange prior to implementation and such affirmative approval will not be given.

⁶³ See Section 3.2(a)(ii) of the BOX Options LLC Agreement.

⁶⁴ "Regulatory Deficiency" is defined as "the operation of the Company (in connection with matters that are not Non-Market Matters) or the BSTX Market (including, but not limited to, the BSTX System) in a manner that is not consistent with the Exchange Rules and/or the SEC Rules governing the BSTX Market or BSTX Participants, or that otherwise impedes the Exchange's ability to regulate the BSTX Market or BSTX Participants or to fulfill its obligations under the Act as an SRO."

⁶⁵ See Section 3.2(a)(iii) of the BOX Options LLC Agreement. See Section 1.1, LLC Agreement.

⁶⁶ 15 U.S.C. 78f(b)(1).

⁶⁷ As discussed above, the Exchange will appoint a Regulatory Director who may, among other things, serve as a Director of any regulatory committee(s). Such individual will also have insight and access to important information related to the Company; for example, while the Regulatory Director may not serve as a Director on Board committees other than authorized regulatory committees, the Regulatory Director nevertheless shall (A) have the right to attend all meetings of the Board and committees thereof; (B) receive equivalent notice of meetings as other Directors; and (C) receive a copy of the meeting materials provided to other Directors, including agendas, action items and minutes for all meetings. (See LLC Agreement § 4.2(c).)

⁶⁸ See Section 3.2(a)(iv) of the BOX Options LLC Agreement.

transferred to the Company after the Exchange makes adequate provision for all regulatory purposes. These provisions ensure that the Exchange has full control over BSTX with respect to its regulated functions and is designed to prevent any owner of BSTX from exercising undue influence over the regulated activities of the Company.

Capital Contributions and Distributions

In the discussion below, the Exchange describes provisions in the LLC Agreement related to capital contributions and distributions by the Company, highlighting areas that vary in comparison to the BOX Options LLC Agreement and/or BOX Holdings LLC Agreement and provides the statutory basis for such variation.

Pursuant to Section 6.1 of the LLC Agreement, all capital contributions contributed to the Company by holders of Units shall be reflected on the books and records of the Company. No interest will be paid on any capital contribution to the Company. No Member will have any personal liability for the repayment of the capital contribution of any Member, and no Member will have any obligation to fund any deficit in its Capital Account. Each Member waived any right to partition the property of the Company or to commence an action seeking dissolution of the Company under the LLC Act. These provisions are substantially the same as those in the BOX Holdings LLC Agreement.⁶⁹

Under Section 6.2 of the LLC Agreement, the Board, in its sole discretion, will determine the capital needs of the Company. If at any time the Board determines that additional capital is required in the interests of the Company, additional working capital shall be raised in such manner as determined by a vote of the Board, including the affirmative vote of at least one Member Director appointed by each Member, but the Board will not have the power to require the Members to make any additional capital contributions. These provisions in the LLC Agreement are substantially the same as those in the BOX Options LLC Agreement, with the exception of the requirement for at least one Member Director appointed by each Member to affirmatively vote on the manner to raise additional working capital.⁷⁰ The Exchange believes that this added provision exists for purposes of commercial fairness and is necessary due to the ownership structure of the Company and that it will foster

cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, consistent with Section 6(b)(5) of the Act.⁷¹

Pursuant to Section 8.1 of the LLC Agreement, if at any time and from time to time the Board determines that the Company has cash that is not required for the operations of the Company, the payment of liabilities or expenses of the Company, or the setting aside of reserves to meet the anticipated cash needs of the Company (“Distributable Cash”), then the Company shall make cash distributions to its Members in the following manner and priority: First, the Company shall make tax distributions (“Tax Distributions”) to the Members to cover each Member’s estimated income tax for that period (or in the event that Distributable Cash is less than the total of all such Tax Amounts, the Company shall distribute the Distributable Cash in proportion to such Tax Amounts). All tax distributions to a Member will be treated as advances against any subsequent distributions to be made to that Member. Subsequent distributions made to the Member shall be adjusted so that when aggregated with all prior distributions to the Member pursuant to those provisions, and with all prior Tax Distributions to the Member, the amount distributed will be equal, as nearly as possible, to the aggregate amount that would have been distributable to that Member pursuant to the LLC Agreement if the LLC Agreement contained no provision for Tax Distributions; second, when, as and if declared by the Board, the Company shall make cash distributions to each of the Members pro rata in accordance with that Member’s respective Percentage Interest. Since the Company does not have the same ownership as BOX Options, the distribution provisions in the LLC Agreement differ from the BOX Options LLC Agreement and BOX Holdings LLC Agreement. These provisions relate to tax and accounting rules to which the Company is subject, due to its ownership structure. As such, these provisions are standard or not novel for a similarly situated commercial business registered as a limited liability company under the laws of the state of Delaware.

Section 8.2 of the LLC Agreement provides that the Company, and the Board on behalf of the Company, shall not make a distribution to any Member on account of its ownership interest in the Company if, and to the extent, such distribution would violate the LLC Act

or other applicable law. This provision in the LLC Agreement is the same as the provision in the BOX Options LLC Agreement and BOX Holdings LLC Agreement.⁷²

Section 9.1 of the LLC Agreement provides that all profits, losses and credits of the Company (for both accounting and tax purposes) for each fiscal year shall be allocated to the Members from time to time (but no less often than once annually and before making any distribution to the Members) pro rata among the Members based on that Member’s respective Percentage Interest, subject to limitations, offsets, chargebacks, deductions and revaluations. Since the Company does not have the same ownership as BOX Options, the allocation of profits and losses provisions in the LLC Agreement differ from the BOX Options LLC Agreement. These provisions relate to tax and accounting rules to which the Company is subject, due to its ownership structure. As such, these provisions are standard or not novel for a similarly situated commercial business registered as a limited liability company under the laws of the state of Delaware.

Under Section 9.9 of the LLC Agreement, any profits or losses resulting from a liquidation, merger or consolidation of the Company, the sale of substantially all the assets of the Company in one or a series of related transactions, or any similar event (and, if necessary, specific items of gross income, gain, loss or deduction incurred by the Company in the fiscal year of the transaction(s)) shall be allocated among the Members so that after those allocations and the allocations required pursuant to capital account adjustments, and immediately before the making of any liquidating distributions to the Members, the Members’ Capital Accounts equal, as nearly as possible, the amounts of the respective distributions to which they are entitled in a winding up. Since the Company does not have the same ownership as BOX Options, the termination and special allocation provisions in the LLC Agreement differ from the BOX Options LLC Agreement. These provisions relate to tax and accounting rules to which the Company is subject, due to its ownership structure. As such, these provisions are standard or not novel for a similarly situated commercial business registered as a limited liability company under the laws of the state of Delaware.

⁶⁹ See Section 6.1 of the BOX Holdings LLC Agreement.

⁷⁰ See Section 6.2 of the BOX Options LLC Agreement.

⁷¹ 15 U.S.C. 78f(b)(5).

⁷² See Section 7.1 of the BOX Options LLC Agreement and Section 8.2 of the BOX Holdings LLC Agreement.

Pursuant to Section 10.2 of the LLC Agreement, the assets of the Company in winding up shall be applied or distributed as follows: First, to creditors of the Company, including Members who are creditors, to the extent otherwise permitted by law, whether by payment or the making of reasonable provisions for the payment thereof, and including any contingent, conditional and unmatured liabilities of the Company, taking into account the relative priorities thereof; second, to the Members and former Members in satisfaction of liabilities under the LLC Act for distributions to those Members and former Members; and third, to the Members in proportion to their respective Percentage Interests. A reasonable reserve for contingent, conditional and unmatured liabilities in connection with the winding up of the business of the Company shall be retained by the Company until the winding up is completed or the reserve is otherwise deemed no longer necessary by the liquidator. These provisions are substantially the same as those in the BOX Holdings LLC Agreement, with the exception of certain provisions that were not included in the LLC Agreement because they are inapplicable to the Company's structure.⁷³

Intellectual Property

In the discussion below, the Exchange describes provisions in the LLC Agreement related to intellectual property of the Company, highlighting areas that vary in comparison to the BOX Options LLC Agreement and/or BOX Holdings LLC Agreement and provides the statutory basis for such variation.

Pursuant to Section 3.2(b) of the LLC Agreement, tZERO will provide to the Company the intellectual property license and services necessary to operate the BSTX trading system as set forth in the LSA and will make the necessary arrangements with any applicable third parties which will permit the Company to be an authorized sublicensee of any required third-party software necessary for Trading on the BSTX System. The intellectual property provisions in the LLC Agreement are materially similar to those in the BOX Options LLC Agreement, although these documents contain certain differences reflecting the fact that, under the LLC Agreement, BSTX has a license with, and receives services from, tZERO pursuant to the LSA and, under the BOX Options LLC Agreement, the

software and technology were provided to BOX Options by MX pursuant to a TOSA. The rights of the Members of each of BOX Options and BSTX with respect to their respective intellectual property are substantially similar.⁷⁴

Under the LSA, tZERO will provide the Company and the Exchange with a perpetual, fully paid up, royalty-free license to use its intellectual property comprising the BSTX trading system. In addition, the LSA provides that tZERO will provide services to the Company, including services related to implementing, administering, maintaining, supporting, hosting, developing, testing and securing the trading system. These services to be provided by tZERO relate to the specialized trading system operated by BSTX and are separate from any administrative or office technology services provided to BSTX by the Exchange discussed above.

Pursuant to the LSA, tZERO retains its ownership of the BSTX trading system and tZERO's trademarks and service marks; provided, however, that the Company will own deliverables, enhancements and other technology that are developed or created by tZERO for the Company, including any related documentation and intellectual property.

Employees of tZERO will provide to the Company the services discussed above under the LSA. This relationship will be similar to the employees of any other technology service provider providing services to the Exchange or a facility of the Exchange. Pursuant to the LSA and Article 15 of the LLC Agreement, tZERO directors, officers and employees will only receive confidential information of the Company or the Exchange, including regulatory information, on a need-to-know basis as it relates to the technology services being provided or specific roles with respect to the Company and the Exchange. Directors, officers and employees of tZERO will be subject to confidentiality obligations with respect to any confidential information they receive in the course of performing their services, including regulatory information. tZERO employees providing technology services to the Company or the Exchange will have offices physically separate from employees of the Company and the Exchange. As discussed below, the Exchange will continue to have all authority to direct its facilities and service providers, including tZERO. tZERO and its

employees will not have operational control of the Company or its systems and will not have authority to make changes to the BSTX System except under the direction of, and after receiving the consent of, the facility under the direction of the Exchange or the Exchange itself. All operational control of BSTX and the BSTX System will be retained by BSTX, under the regulatory authority of the Exchange, except for regulatory and surveillance systems which will be controlled directly by the Exchange. tZERO will provide technology support services to the Exchange and the proposed facility, BSTX.

Non-Competition

Section 16.1 of the LLC Agreement provides that, for so long as it holds, directly or indirectly, a combined Percentage Interest in the Company of five percent (5%) or more, a Member will not hold or invest in more than five percent (5%) of, or participate in the creation and/or operation of, any U.S.-based market for the secondary trading of securities with a blockchain component or in any person engaged in the creation and/or operation of any U.S.-based market for the secondary trading of securities with a blockchain component. The non-competition provision is substantially the same as the non-competition provision in the BOX Holdings LLC Agreement.⁷⁵

Changes in Ownership of the Company

In the discussion below, the Exchange describes provisions in the LLC Agreement related to changes in ownership of the Company, highlighting areas that vary in comparison to the BOX Options LLC Agreement and/or BOX Holdings LLC Agreement and provides the statutory basis for such variation.

Section 7.1(a) of the LLC Agreement provides that no person will directly or indirectly, whether voluntarily, involuntarily, by operation of law or otherwise, dispose of, sell, alienate, assign, exchange, participate, subparticipate, encumber, or otherwise transfer in any manner (each, a "Transfer") its Units unless prior to that Transfer the transferee is approved by a vote of the Board. To be eligible for Board approval, a proposed transferee must be of high professional and financial standing, be able to carry out its duties as a Member hereunder, if admitted as a Member, and be under no regulatory or governmental bar or disqualification. Notwithstanding the

⁷³ See Section 10.2 of the BOX Holdings LLC Agreement.

⁷⁴ See Article 17 of the LLC Agreement and Article 13 of the BOX Options LLC Agreement.

⁷⁵ See Section 16.1 of the BOX Holdings LLC Agreement.

foregoing, registration as a broker-dealer or self-regulatory organization is not required to be eligible for Board approval. However, the following will not be included in the definition of "Transfer": Transfers among Members, transfers to any Person directly or indirectly owning, controlling or holding with power to vote all of the outstanding voting securities of and equity or beneficial interests in that Member, or transfers to any Person that is a wholly owned Affiliate of a transferring Member. A holder of Units will provide prior written notice to the Exchange of any proposed Transfer. Any Transfer which violates the Transfer restrictions in the LLC Agreement will be void and ineffectual and will not bind or be recognized by the Company.

Section 7.1(b) of the LLC Agreement establishes that a person will be admitted to the Company as an additional or substitute Member of the Company only upon that person's execution of a counterpart of the LLC Agreement to evidence its written acceptance of the terms and provisions of the LLC Agreement, and acceptance thereof by resolution of the Board, which acceptance may be given or withheld in the sole discretion of the Board; if that person is a transferee, its agreement in writing to its assumption of the obligations under the LLC Agreement of its assignor, and acceptance thereof by resolution of the Board; if that person is a transferee, a determination by the Board that the Transfer was permitted by the LLC Agreement; and approval of the Board. Whether or not a transferee who acquired any Units has accepted in writing the terms and provisions of the LLC Agreement and assumed in writing the obligations hereunder of its predecessor in interest, that transferee will be deemed, by the acquisition of those Units, to have agreed to be subject to and bound by all the obligations of the LLC Agreement with the same effect and to the same extent as any predecessor in interest of that transferee. Notwithstanding the foregoing, any Person to which the Company issues new Class B Units shall be automatically admitted as a Member upon such Person's execution of a counterpart of the LLC Agreement.⁷⁶ Pursuant to Section 7.1(c) of the LLC Agreement, all costs incurred by the

Company in connection with the admission of a substituted Member will be paid by the transferor Member. The transfer provisions in Section 7.1 of the LLC Agreement are not contained in the BOX Options LLC Agreement; however, the Exchange notes that the provisions of Section 7.1 are substantially based on provisions in the BOX Holdings LLC Agreement.⁷⁷

Pursuant to Section 7.2 of the LLC Agreement, the Company will have a right of first refusal if a Member desires to Transfer its Units, and obtains a bona fide offer therefor from a third-party transferee. Further, Section 7.3 of the LLC Agreement provides that, if the Company does not elect to exercise its right of first refusal, the non-transferring Member(s) next have a right of first refusal. The provisions in Sections 7.2 and 7.3 of the LLC Agreement are substantially based on provisions found in the BOX Holdings LLC Agreement, with certain variations to account for differences in corporate and ownership structure.⁷⁸ The Exchange believes that such variations are necessary to ensure proper application of the LLC Agreement's provisions to the Company, which serve to remove impediments to and perfect the mechanism of a free and open market and a national market system, consistent with Section 6(b)(5) of the Act.⁷⁹ Further, the Exchange believes that the variations in Sections 7.2 and 7.3 of the LLC Agreement that tailor those provisions to the corporate and ownership structure of BSTX would help ensure that persons subject to the Exchange's jurisdiction are able to navigate and more readily understand the LLC Agreement. The Exchange believes that this, in turn, would be consistent with Section 6(b)(1) of the Act⁸⁰ because it would help ensure that the Exchange, including in its operation of facilities, is so organized and has the capacity to be able to carry out the purposes of the Act.

Pursuant to Section 7.4 of the LLC Agreement, no Transfer may occur if the Transfer could cause a termination of the Company, could cause a termination of the Company's status as a partnership or cause the Company to be treated as a publicly traded partnership for federal income tax purposes, is prohibited by any securities laws, is prohibited by the LLC Agreement, or is to a minor or incompetent person.

Section 7.4(e) of the LLC Agreement requires that a Member will provide the Company with written notice fourteen (14) days prior, and the Company will provide the Commission and the Exchange with written notice ten (10) days prior, to the closing date of any acquisition that results in that Member's Percentage Interest, alone or together with any related person of that Member, meeting or crossing the threshold level of 5% or the successive 5% Percentage Interest levels of 10% and 15%. Any person that, either alone or together with its related persons, owns, directly or indirectly, of record or beneficially, five percent (5%) or more of the then outstanding Units will, immediately upon acquiring knowledge of its ownership of five percent (5%) or more of the then outstanding Units, give the Company written notice of that ownership. In addition, Section 7.4(f) of the LLC Agreement provides that any Transfer that results in the acquisition and holding by any person, alone or together with its related persons, of an aggregate Percentage Interest level which meets or crosses the threshold level of 20% or any successive 5% Percentage Interest level (*i.e.*, 25%, 30%, etc.) is also subject to the rule filing process pursuant to Section 19 of the Act.

Under Section 7.4(g) of the LLC Agreement, unless it does not directly or indirectly hold any interest in a Member, a Controlling Person (as defined below) of a Member will be required to execute an amendment to the LLC Agreement upon establishing a Controlling Interest (as defined below) in any Member that, alone or together with any related persons of that Member, holds a Percentage Interest in the Company equal to or greater than 20%. This amendment will be substantially in the form of the instrument of accession attached as Exhibit 5B hereto [sic] and provide that the Controlling Person will agree to become a party to the LLC Agreement and to abide by all of its provisions, to the same extent and as if they were Members. These amendments to the LLC Agreement will be subject to the rule filing process pursuant to Section 19 of the Act. The rights and privileges, including all voting rights, of the Member in whom a Controlling Interest is held, directly or indirectly, under the LLC Agreement and the LLC Act will be suspended until the amendment has become effective pursuant to Section 19 of the Act or the Controlling Person no longer holds, directly or indirectly, a Controlling Interest in the Member.⁸¹ As

⁷⁶ Automatic admission of Class B Units as Members upon such Person's execution of a counterpart of the LLC Agreement is not included in the BOX Holdings LLC Agreement because BOX Holdings does not have a non-voting class of units similar to the non-voting Class B Units issued by the Company to service providers to the Company under the authority of the Board.

⁷⁷ See Section 7.1 of the BOX Holdings LLC Agreement.

⁷⁸ See Sections 7.2 and 7.3 of the BOX Holdings LLC Agreement.

⁷⁹ 15 U.S.C. 78f(b)(5).

⁸⁰ 15 U.S.C. 78f(b)(1).

⁸¹ See *supra* note 21.

a result, any new Member or other direct or indirect owner of an equity interest in BSTX, whether by transfer of such equity interest from an existing owner or otherwise, will be subject to the same requirements as all other Members, namely that it will be required to execute an instrument of accession to the LLC Agreement and be subject to the rule filing process if the new Member holds, directly or indirectly, a Controlling Interest in BSTX.

In accordance with Section 7.4(h) of the LLC Agreement and as discussed above, in the event any Member, or any Related Person of such Member, is approved by the Exchange as a BSTX Participant pursuant to the Exchange Rules, and such Member owns more than 20% of the Units, alone or together with any Related Person of such Member (Units owned in excess of 20% being referred to as “Excess Units”), the Member and its appointed Member Directors shall have no voting rights whatsoever with respect to any action relating to the Company nor shall the Member or its appointed Member Directors, if any, be entitled to give any proxy in relation to a vote of the Members, in each case solely with respect to the Excess Units held by such Member; provided, however, that whether or not such Member or its appointed Member Directors, if any, otherwise participates in a meeting in person or by proxy, such Member’s Excess Units shall be counted for quorum purposes and shall be voted by the person presiding over quorum and vote matters in the same proportion as the Units held by the other Members are voted (including any abstentions from voting). In addition, an effective rule filing pursuant to Section 19 of the Act shall be required prior to any Member, or any Related Person of such Member, becoming a BSTX Participant if such Member, alone or together with any Related Persons of such Member, has the right to appoint more than 20% of the Directors entitled to vote and, unless a rule filing authorizing the foregoing is first effective, such Member, or any Related Person of such Member, shall not be registered as a BSTX Participant. The Exchange notes that Section 7.4 of the Company’s LLC Agreement is identical in substance to provisions of the BOX Holdings LLC Agreement.⁸²

In addition to the provisions discussed above, Section 5 of the LLC Agreement includes provisions that relate to changes in ownership of the Company. Because BOX Options is

wholly-owned by BOX Holdings, the LLC Agreement differs from the BOX Options LLC Agreement. Under Section 5.5 of the LLC Agreement, a Member will cease to be a Member of the Company upon the Bankruptcy or the involuntary dissolution of that Member. Further, Section 5.8 of the LLC Agreement allows the Board, by unanimous vote and after appropriate notice and opportunity for hearing, to suspend or terminate a Member’s voting privileges or membership in the Company for three potential reasons: (i) In the event the Board determines in good faith that such Member is subject to a “statutory disqualification,” as defined in Section 3(a)(39) of the Act; (ii) in the event the Board determines in good faith that such Member has violated a material provision of this Agreement, or any federal or state securities law; or (iii) in the event the Board determines in good faith that such action is necessary or appropriate in the public interest or for the protection of investors. The Exchange believes that limiting the ability to participate in the Company for Members who may act in contravention of legal or ethical standards may promote just and equitable principles of trade, and, in general, protects investors and the public interest, consistent with Section 6(b)(5) of the Act.⁸³ Further, the Exchange believes that the ability to suspend or terminate a Member’s voting privileges or membership in the Company as described above would be consistent with Section 6(b)(1) of the Act.⁸⁴ This is because such measures in respect of Members who act in contravention of legal or ethical standards would help ensure that the Exchange, including in its operation of facilities, is so organized and has the capacity to be able to carry out the purposes of the Act, including the prevention of inequitable and unfair practices.

Finally, the Exchange notes that Section 18.1 of the Company’s LLC Agreement provides that amendments to the LLC Agreement must be approved by the Board, including one Member Director appointed by each of BOX Digital and tZERO, and any amendment of a provision specific to any Class, Member, or the Exchange requires the consent of holders of a majority of the outstanding Units of such Class, or such Member or the Exchange (as applicable). In addition, the Company shall provide prompt notice to the Exchange of any amendment, modification, waiver or supplement to the Agreement formally

presented to the Board for approval and the Exchange shall review each such amendment, modification, waiver or supplement and, if such amendment is required, under Section 19 of the Act and the rules promulgated thereunder, to be filed with, or filed with and approved by, the SEC before such amendment may be effective, then such amendment shall not be effective until filed with, or filed with and approved by, the SEC, as the case may be.⁸⁵ These provisions are similar to provisions in the BOX Holdings LLC Agreement but differ in details related to the different ownership structure of the Company.⁸⁶

Regulation of the Company

In the discussion below, the Exchange describes provisions in the LLC Agreement related to regulation of the Company, highlighting areas that vary in comparison to the BOX Options LLC Agreement and/or BOX Holdings LLC Agreement and provides the statutory basis for such variation.

Generally, Section 3.2 of the LLC Agreement, which is identical in substance to a provision in the BOX Options LLC Agreement, provides that the Exchange has authority to act as the SRO for the Company, will provide the regulatory framework for the BSTX Market and will have regulatory responsibility for the activities of the BSTX Market.⁸⁷ In addition, the Exchange will provide regulatory services to the Company pursuant to the Facility Agreement. Nothing in the LLC Agreement shall be construed to prevent the Exchange from allowing the Company to perform activities that support the regulatory framework for the BSTX Market, subject to oversight by the Exchange. This provision ensures that the Exchange has full regulatory control over BSTX, which is designed to prevent any owner of BSTX from exercising undue influence over the regulated activities of the Company.

Section 15 of the LLC Agreement deals with how the Company will govern the handling of confidential information, as it relates to the securities regulations and otherwise. All of the provisions in Section 15 of the LLC Agreement are substantively similar to provisions in the BOX Options LLC Agreement, except where

⁸⁵ A proposed rule change can also become effective by operation of law. *See* 15 U.S.C. 78s(b)(2).

⁸⁶ *See* Section 18.1 of the BOX Holdings LLC Agreement.

⁸⁷ *See* Section 3.2 of the BOX Options LLC Agreement.

⁸² *See* Section 7.4 of the BOX Holdings LLC Agreement.

⁸³ 15 U.S.C. 78f(b)(5).

⁸⁴ 15 U.S.C. 78f(b)(1).

noted below.⁸⁸ Under Sections 15.1 and 15.2(a) of the LLC Agreement, subject to certain exceptions set forth below, no Member will make any public disclosures concerning the LLC Agreement without the prior approval of the Company. Each Member and the Exchange may only use confidential information of the Company in connection with the activities contemplated by the LLC Agreement and other written agreements and pursuant to the Act and the rules and regulations thereunder. Furthermore, Section 15.4 of the LLC Agreement provides that representatives of the parties will meet to institute confidentiality procedures and discuss confidentiality and disclosure issues.

Pursuant to Section 15.2(b) of the LLC Agreement, each of the Members and the Exchange may disclose confidential information of the Company only to its respective directors, officers, employees and agents who have a reasonable need to know the information. Also, such individuals may disclose confidential information of the Company to the extent required by applicable securities or other laws, a court or securities regulators, including the Commission and the Exchange.

Section 15.3 of the LLC Agreement requires that each Member and the Exchange will hold all non-public information concerning the other Members or the Exchange in strict confidence, unless disclosure to an applicable regulatory authority is necessary or appropriate or unless compelled to disclose by judicial or administrative process or required by law. If a Member or the Exchange is compelled to disclose any Member Information in connection with any necessary regulatory approval or by judicial or administrative process, it will promptly notify the disclosing party to allow the disclosing party to seek a protective order.

Pursuant to Section 15.5 of the LLC Agreement, nothing in the LLC Agreement will be interpreted as to limit or impede the rights of any Governmental Authority,⁸⁹ including the SEC, pursuant to the federal securities laws and rules and

regulations thereunder, and the Exchange to access and examine applicable confidential information pursuant to the federal securities laws and the rules and regulations thereunder, or to limit or impede the ability of any directors, officers, employees, advisors or agents of the Company and any directors, officers, employees, advisors or agents of the Members to disclose that confidential information to any Governmental Authority, including the SEC, or the Exchange. Under Section 15.6 of the LLC Agreement, confidential information of the Company or the Exchange pertaining to regulatory matters (including but not limited to disciplinary matters, trading data, trading practices and audit information) will not be made available to any persons other than to the Company's Directors, officers, employees, advisors and agents that have a reasonable need to know the contents thereof; will be retained in confidence by the Company and the Directors, officers, employees, advisors and agents of the Company; and will not be used for any non-regulatory purpose. Nothing in the LLC Agreement will be interpreted as to limit or impede the rights of any Governmental Authority, including the SEC, and the Exchange to access and examine that confidential information pursuant to the federal securities laws and the rules and regulations thereunder, or to limit or impede the ability of any Directors, officers, employees, advisors and agents of the Company to disclose that confidential information to any Governmental Authority, including the SEC, or the Exchange. These are substantially the same provisions that are contained in the BOX Options LLC Agreement, except that these provisions also clarify that advisors are included with Directors, Officers, employees and agents of the Company and provides that any Governmental Authority, including the SEC, can access and examine confidential information, pursuant to the federal securities laws and rules and regulations thereunder.⁹⁰

Finally, Section 18.8 of the LLC Agreement establishes that the Company will not operate as a facility of the Exchange until this rule filing is effective. Upon effectiveness, the Commission and the Exchange will then have regulatory oversight responsibilities with respect to the Company and references in the LLC Agreement to the Exchange, the Commission, any regulation or oversight

of the Company by the Commission or the Exchange, and any participation in the affairs of the Company by the Commission or the Exchange, will take effect. The execution of the LLC Agreement by the Exchange will not be required until the approval is obtained, at which time the Exchange will become a party to the LLC Agreement. This provision is not included in the BOX Options LLC Agreement because it would not be applicable. By not operating the Company until this rule filing is effective, the Exchange believes it is fostering cooperation and coordination with persons engaged in regulating (e.g., the Commission), clearing, settling, processing information with respect to, and facilitating transactions in securities, consistent with Section 6(b)(5) of the Act.⁹¹

Regulatory Jurisdiction Over Members

In the discussion below, the Exchange describes provisions in the LLC Agreement related to regulatory jurisdiction over Members by the Company, highlighting areas that vary in comparison to the BOX Options LLC Agreement and/or BOX Holdings LLC Agreement and provides the statutory basis for such variation.

Pursuant to Section 11.1 of the LLC Agreement, which is similar in substance to a provision in the BOX Holdings LLC Agreement, the Board will cause to be entered in appropriate books, kept at the Company's principal place of business, all transactions of or relating to the Company.⁹² Each Member will have the right to inspect and copy those books and records, excluding regulatory and disciplinary information. The Board will not have the right to keep confidential from the Members any information that the Board would otherwise be permitted to keep confidential pursuant to § 18–305(c) of the LLC Act, except for information required by law or by agreement with any third party to be kept confidential. The Company's independent auditor will be an independent public accounting firm selected by the Board. To the extent related to the operation or administration of the Exchange or the BSTX Market, all books and records of the Company and its Members will be maintained at a location within the United States, the books, records, premises, directors, officers, employees and agents of the Company and its Members will be deemed to be the books, records, premises, directors,

⁸⁸ See Article 12 of the BOX Options LLC Agreement.

⁸⁹ "Governmental Authority" means any United States federal, state or local government or political subdivision thereof, or any agency or instrumentality of such government or political subdivision, or any self-regulated organization or other non-governmental regulatory authority or quasi-governmental authority (to the extent that the rules, regulations or orders of such organization or authority have the force of law), or any arbitrator, court or tribunal of competent jurisdiction. See Section 1.1, LLC Agreement.

⁹⁰ See Sections 12.5 and 12.6 of the BOX Options LLC Agreement.

⁹¹ 15 U.S.C. 78f(b)(5).

⁹² See Section 11.1 of the BOX Holdings LLC Agreement.

officers, employees and agents of the Exchange for the purposes of, and subject to oversight pursuant to, the Act, and the books and records of the Company and its Members will be subject at all times to inspection and copying by the Commission and the Exchange.

Under Section 18.6(a) of the LLC Agreement, to the extent they are related to Company activities, the books, records, premises, officers, directors, agents, and employees of the Member will be deemed to be the books, records, premises, officers, directors, agents, and employees of the Exchange for the purpose of and subject to oversight pursuant to the Act. Further, pursuant to Section 18.6(b) of the LLC Agreement, the Company, the Members and the officers, directors, employees and agents of each, by virtue of their acceptance of those positions, will be deemed to irrevocably submit to the jurisdiction of the U.S. federal courts, the Commission and the Exchange for purposes of any suit, action or proceeding pursuant to U.S. federal securities laws, the rules or regulations thereunder, arising out of, or relating to, activities of the Exchange and the Company, and Delaware state courts for any matter relating to the organization or internal affairs of the Company, and will be deemed to waive, and agree not to assert by way of motion, as a defense or otherwise in any suit, action or proceeding, any claims that they are not personally subject to the jurisdiction of the U.S. federal courts, the Commission, the Exchange or Delaware state courts, as applicable, that the suit, action or proceeding is an inconvenient forum or that the venue of the suit, action or proceeding is improper, or that the subject matter hereof may not be enforced in or by those courts or agencies. The Company, the Members and the officers, directors, employees and agents of each, by virtue of their acceptance of those positions, also agree that they will maintain an agent in the United States for the service of process of a claim arising out of, or relating to, the activities of the Exchange and the Company. These provisions are substantially similar to provisions of the BOX Options LLC Agreement.⁹³

Pursuant to Section 18.6(c) of the LLC Agreement, with respect to obligations under the LLC Agreement related to confidentiality regulation, jurisdiction and books and records, the Company, the Exchange, and each Member will ensure that directors, officers and employees of the Company, the Exchange, and each Member consent in

writing to the applicability of the applicable provisions to the extent related to the operation or administration of the Exchange or the BSTX Market. This provision is substantially the same as the provision contained in the BOX Options LLC Agreement, with the exception of the deletion of a reference to privacy rules in Canada, which are not applicable to the current Members of the Company.⁹⁴ The Exchange believes that allowing only applicable laws to be referenced in the LLC Agreement helps to ensure that proper legal standards apply to the Company, which may foster cooperation and coordination with persons engaged in regulating transactions in securities, consistent with Section 6(b)(5) of the Act.⁹⁵ Further, the Exchange believes that basing the provisions described above on the BOX Options LLC Agreement but omitting terms that are not applicable would help ensure that persons subject to the Exchange's jurisdiction are able to navigate and more readily understand the LLC Agreement. The Exchange believes that this, in turn, would be consistent with Section 6(b)(1) of the Act⁹⁶ because it would help ensure that the Exchange, including in its operation of facilities, is so organized and has the capacity to be able to carry out the purposes of the Act.

Amendments to LLC Agreement

In the discussion below, the Exchange describes provisions in the LLC Agreement related to amendments to the LLC Agreement, highlighting areas that vary in comparison to the BOX Options LLC Agreement and/or BOX Holdings LLC Agreement and provides the statutory basis for such variation.

Section 18.1 of the LLC Agreement, which is substantially similar to a provision in the BOX Holdings LLC Agreement,⁹⁷ provides that the LLC Agreement may only be amended by an agreement in writing approved by the Board, including at least one Member Director appointed by each Member, without the consent of any Member or other person. In addition, any terms specific to any Class, or Member or to the Exchange may not be altered or adversely affect that Member or the Exchange without the prior written consent of holders of a majority of the outstanding Units of such Class, or such Member or the Exchange as applicable. The Company will provide prompt notice to the Exchange of any

amendment, modification, waiver or supplement to the LLC Agreement formally presented to the Board for approval and the Exchange will review each amendment, modification, waiver or supplement and, if that amendment is required, under Section 19 of the Act and the rules promulgated thereunder, to be filed with, or filed with and approved by, the Commission before that amendment may be effective, then that amendment will not be effective until filed with, or filed with and approved by, the Commission, as the case may be. If the Exchange ceases to be the SRO authority of the Company, the Exchange will no longer be a party to the LLC Agreement and thereafter the provisions of the LLC Agreement will not apply to the Exchange except for the provisions referenced in Section 18.12, which will survive.

Additional Provisions

As previously mentioned, BSTX is a Delaware limited liability company. As such, the LLC Agreement contains numerous provisions that are standard or not novel for a similarly situated commercial business registered as a limited liability company under the laws of the state of Delaware.⁹⁸ The Exchange believes that these provisions are consistent with Section 6(b)(1) of the Act⁹⁹ because they are consistent with corporate governance practices, generally, and they would help ensure that the Exchange, including in its operation of facilities, is so organized and has the capacity to be able to carry out the purposes of the Act.

Exchange Organization

As more fully described in the Multiple Facilities Filing,¹⁰⁰ the bylaws of the Exchange (the "Exchange Bylaws") require that, upon the Company becoming a facility of the Exchange, at least one member of the Board would be selected from among the officers, directors and employees of BSTX Participants (a "Participant Director").¹⁰¹ The Executive Committee of the Exchange, if any, is required to include at least one Participant Director from BSTX and a quorum for the transaction of business must include at least one Participant Director from one

⁹⁸ See LLC Agreement Sections 2.1, 2.2, 2.4, 2.5, 2.6, 2.7, 3.1, 4.2, 4.5, 4.6, 4.7, 4.8, 4.9, 4.11, 5.1, 5.2, 5.3, 5.4, 5.6, 5.7, 6.3, 6.4, 6.5, 7.5, 7.6, 7.7, 8.3, 9.2, 9.3, 9.4, 9.5, 9.6, 9.7, 9.8, 10.3, 10.4, 11.2, 11.3, 11.4, 11.5, 11.6, 12, 13.1, 14, 16.2, 17, 18.2, 18.3, 18.4, 18.5, 18.7, 18.9, 18.10, 18.11, and 18.12.

⁹⁹ 15 U.S.C. 78f(b)(1).

¹⁰⁰ See Securities Exchange Act Release No. 888934 May 22, 2020, 85 FR 32085 May 28, 2020.

¹⁰¹ See Exchange Bylaws Section 4.02.

⁹³ See Section 14.6 of the BOX Options LLC Agreement.

⁹⁴ See Section 14.6(c) of the BOX Options LLC Agreement.

⁹⁵ 15 U.S.C. 78f(b)(5).

⁹⁶ 15 U.S.C. 78f(b)(1).

⁹⁷ See Section 18.1 of the BOX Holdings LLC Agreement.

of the Exchange's facilities.¹⁰² A Participant Director could serve on other Board committees but would be prohibited from serving on the Compensation and Regulatory Oversight Committees.¹⁰³ The Exchange's Hearing Committee is not comprised of directors of the Exchange but does include Exchange Facility Participants, which could include one or more BSTX Participants.¹⁰⁴ The Exchange Bylaws also provide that each facility of the Exchange be entitled to designate a "Facility Director" to serve on the Board. The Facility Director could serve on Board committees, including any Executive Committee of the Board,¹⁰⁵ but would be prohibited from serving on the Compensation and Regulatory Oversight Committees.¹⁰⁶

Also as more fully described in the Multiple Facilities Filing, the Exchange Bylaws require that, upon the Company becoming a facility of the Exchange, at least one member of the Exchange Nominating Committee would be selected from among the officers, directors and employees of BSTX Participants (a "Participant Representative").¹⁰⁷ The Exchange Bylaws also provide that each facility of the Exchange be entitled to designate a "Facility Representative" to serve on the Exchange Nominating Committee.¹⁰⁸

As soon as practicable after the commencement of operations of BSTX as a new facility of the Exchange, a Participant Director, Participant Representative, Facility Director and Facility Representative will be appointed by the Exchange Board from among the eligible individuals with respect to the new facility and such individuals shall serve in such respective capacities until the first annual meeting of the Exchange Members following such appointment, when the regular selection processes shall govern.¹⁰⁹

2. Statutory Basis

In addition to the sections above that discuss provisions of the LLC Agreement, amendments to the LLC Agreement and variations from the BOX Options LLC Agreement and/or BOX Holdings LLC Agreement and their associated statutory bases, the Exchange believes that the proposal is consistent with the requirements of Section 6(b) of

the Act,¹¹⁰ in general, and furthers the objectives of Section 6(b)(1),¹¹¹ in particular, in that it enables the Exchange to be so organized so as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its Exchange Facility Participants and persons associated with its Exchange Facility Participants, with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange. The Exchange also believes that this filing furthers the objectives of Section 6(b)(5) of the Act¹¹² in that it is designed to facilitate transactions in securities, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest.

The Exchange believes that the provisions in the Exchange Bylaws that BSTX Participants will be represented by a Participant Director on the BOX Exchange Board and a Participant Representative on the Exchange Nominating Committee and that they will be chosen by BSTX Participants provides for the fair representation of BSTX Participants in the selection of directors and the administration of BOX Exchange and is consistent with the requirement in Section 6(b)(3) of the Act.¹¹³ This requirement helps to ensure that BSTX Participants have a voice in the use of self-regulatory authority and that an exchange is administered in a way that is equitable to all those who trade on its market or through its facilities.¹¹⁴ In addition, the Exchange believes the provision in the Exchange Bylaws that a Facility Director representing the Company would serve on the BOX Exchange Board and a Facility Representative would serve on the BOX Exchange Nominating Committee provides additional protection for both the Company and

BSTX Participants and helps to ensure these entities have a voice in the use of self-regulatory authority and that an exchange is administered in a way that is equitable to all those who trade on its market or through its facilities.

No Members of BSTX and no Affiliates of such Members are currently Exchange Facility Participants. No Members of BSTX are expected to be BSTX Participants when BSTX begins operations as a facility of the Exchange. Nevertheless, the Exchange believes the provisions discussed above, limiting BSTX Participants to a maximum of 20% voting power at the proposed facility, BSTX, and limiting Exchange Facility Participants to a maximum of 20% economic ownership in the Exchange and 20% voting power at the Exchange, are consistent with the requirements of the Act and Section 6(b)(1) thereof, which requires, in part, an exchange be so organized and have the capacity to carry out the purposes of the Act.¹¹⁵ These limitations are designed to help prevent a BSTX Participant from exercising undue control over the operation of the facility and help prevent an Exchange Facility Participant from exercising undue control over the operation of the Exchange. These limitations are also designed to help ensure the Exchange is able to effectively carry out its regulatory obligations under the Act and its facility, BSTX, is able to effectively carry out its regulatory obligations as a facility of the Exchange under the Act. In addition, these limitations are designed to address conflicts of interests that could arise from a BSTX Participant owning interests in BSTX, a proposed facility of the Exchange, or in the Exchange itself. Without such limitations, a BSTX Participant's interest in the Exchange or its facility, BSTX, could become so large as to cast doubts on whether the Exchange and its facility, BSTX, may fairly and objectively exercise self-regulatory responsibilities with respect to such BSTX Participant.¹¹⁶ If a BSTX Participant became a controlling owner of the Exchange, BSTX could seek to exercise the controlling influence by directing the Exchange or its facility, BSTX, to refrain from, or the Exchange or BSTX could hesitate to, diligently monitor and conduct surveillance of the BSTX Participant's conduct or diligently enforce the Exchange's rules and the federal securities laws with respect to

¹¹⁰ 15 U.S.C. 78f(b).

¹¹¹ 15 U.S.C. 78f(b)(5).

¹¹² 15 U.S.C. 78f(b)(5).

¹¹³ 15 U.S.C. 78f(b)(3).

¹¹⁴ See, e.g., Securities Exchange Act Release No. 53128 (January 13, 2006), 71 FR 3550 (January 23, 2006) (granting the exchange registration of Nasdaq Stock Market, Inc.) ("Nasdaq Order"), and 58375 (August 18, 2008), 73 FR 49498 (August 21, 2008) ("BATS Order"), supra note 27. See also Securities Exchange Act Release No. 53382 (February 27, 2006), 71 FR 11251 (March 6, 2006) ("NYSE/Archipelago Merger Approval Order").

¹¹⁵ 15 U.S.C. 78f(b)(1).

¹¹⁶ See, e.g., Securities Exchange Act Release No. 61698 (March 12, 2010), 75 FR 13151 (March 18, 2010) ("DirectEdge Exchanges Order") and BATS Order, supra note 27.

¹⁰² See Exchange Bylaws Section 6.04.

¹⁰³ See Exchange Bylaws Sections 6.06 and 6.07.

¹⁰⁴ See Exchange Bylaws Section 6.08(a).

¹⁰⁵ See Exchange Bylaws Section 6.04.

¹⁰⁶ See Exchange Bylaws Sections 6.06 and 6.07.

¹⁰⁷ See Exchange Bylaws Section 4.06(a).

¹⁰⁸ See Exchange Bylaws Section 4.06(a).

¹⁰⁹ See Section 4.02, Exchange Bylaws.

conduct by a BSTX Participant that violates such provisions. As such, these requirements are expected to minimize the potential that a BSTX Participant or any other Exchange Facility Participant could use its ownership to improperly interfere with or restrict the ability of the Exchange or its facility, BSTX, to effectively carry out its regulatory responsibilities under the Act, particularly with Section 6(b)(1) thereof, which requires, in part, an exchange be so organized and have the capacity to carry out the purposes of the Act.¹¹⁷

As discussed above, the Exchange at all times has, and will continue to have, regulatory authority over its facilities, including the proposed facility, BSTX. The Exchange's powers and authority under the Facility Agreement ensure that the Exchange has full regulatory control over BSTX, which is designed to prevent any owner of BSTX from exercising undue influence over the regulated activities of the Company. The Exchange shall receive notice of all planned or proposed changes to BSTX (other than Non-Market Matters). This authority ensures that while BSTX operates as a facility of the Exchange, it will be required to submit to any such changes to the Exchange for approval and the Exchange will have the right to direct BSTX to make any modifications deemed necessary or appropriate by the Exchange to resolve any Regulatory Deficiency. This regulatory authority overrides any authority of BSTX management, its Members or its Board regardless of any Member's level of ownership or control of the Board at the facility level.

The Exchange is the entity that will have and exercise regulatory oversight of the proposed facility, BSTX. As discussed above, the Exchange notes the existing ownership limits of 20% voting power and 40% economic ownership currently applicable to all owners of the Exchange, are not changing. Accordingly, the Exchange believes these existing ownership limits will help to ensure the independence of the Exchange's regulatory oversight of BSTX and facilitate the ability of the Exchange to carry out its regulatory responsibilities and operate in a manner consistent with the Act. The Exchange further believes these ownership limits, which apply to its current facility, continue to be appropriate in connection with the proposed new facility and are consistent with the requirements of the Act and Section 6(b)(1) thereof, which requires, in part, an exchange be so organized and have

the capacity to carry out the purposes of the Act.¹¹⁸

As discussed above, the SEC will be required to be notified if a Member of the facility exceeds 5%, 10% or 15% ownership in the Company and rule filings are required when a Member, together with its Related Persons, crosses above 20% or any subsequent 5% increment. These are the same provisions as are contained in the BOX Holdings LLC Agreement. The Exchange believes these proposed notification provisions are consistent with existing provisions in the BOX Holdings LLC Agreement for the Exchange's current facility and are also consistent with the Act, including Section 6(b)(1), which requires, in part, an exchange to be so organized and have the capacity to carry out the purposes of the Act.¹¹⁹ In particular, SEC notification of ownership interests exceeding certain percentage thresholds can help improve the Commission's ability to effectively monitor and surveil for potential undue influence and control over the operation of the Exchange.

Subject to the regulatory oversight by the Exchange, the proposed facility's Board has full authority to manage the development, operations, business and affairs of the Company without the need for any approval of the Members. A Member does not have authority to decide matters related to the operations of the Company, except by exercising its right, if any, to appoint Directors. As discussed above, the Board of the proposed facility will consist of six (6) Directors, including five (5) voting Directors and one non-voting Regulatory Director appointed by the Exchange. Regardless of its ownership level, each of tZERO and BOX Digital will have the right to appoint only two Directors, comprising a maximum of 40% of all voting Directors on the facility's Board. The remaining voting Director on the Board will be an Independent Director. Accordingly, the Exchange believes the proposed facility, BSTX, will be so organized as to avoid undue influence by a Member and to ensure the Exchange has the capacity to carry out the purposes of the Act.

As discussed above, as long as the Company is a facility of the Exchange pursuant to Section 3(a)(2) of the Act, the Exchange will have the right to appoint a Regulatory Director to serve as a Director. The Regulatory Director must be a member of the senior management of the regulation staff of the Exchange. The Company has an Independent Director to avoid either Member from

controlling or creating deadlock on the Board. The presence of a Regulatory Director selected by the Exchange on the Board is identical to the longstanding practice at the Exchange's other facility, BOX Options. The Exchange believes that the proposed board structure, and in particular, the inclusion of the proposed Independent Director and Regulatory Director, will promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, consistent with Section 6(b)(5) of the Act.¹²⁰ Further, the Exchange believes that inclusion of the Regulatory Director on the BSTX Board would also be consistent with Section 6(b)(1) of the Act. This is because the Regulatory Director is required to be someone who is a member of the senior management of the regulation staff of the Exchange and is therefore a person who is knowledgeable of the rules of the Exchange and the regulations applicable to it and, in turn, is someone who would be well positioned to help ensure the Exchange, including in the operation of any facilities, continues to be so organized and has the capacity to carry out the purposes of the Act, including to prevent inequitable and unfair practices.

As discussed above, the Company is not permitted to take any action with respect to a Major Action unless approved by the Board, including the affirmative vote of all then serving Member Directors acting at a meeting. The Exchange believes that, in addition to the regulatory oversight of the Exchange and the other safeguards described above, the requirement that all Member Directors of the facility, not just the Member Directors of a single Member, must approve Major Actions will promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, consistent with Section 6(b)(5) of the Act. In addition, such requirements enhance the ability of the Exchange and

¹¹⁸ 15 U.S.C. 78f(b)(1).

¹¹⁹ 15 U.S.C. 78f(b)(1).

¹²⁰ 15 U.S.C. 78f(b)(5).

¹¹⁷ 15 U.S.C. 78f(b)(1).

its proposed facility, BSTX, to effectively carry out its regulatory responsibilities under the Act, particularly with Section 6(b)(1) thereof, which requires, in part, an exchange be so organized and have the capacity to carry out the purposes of the Act.

Although the Company is not independently responsible for regulation, its activities with respect to the operation of the Company must be consistent with, and not interfere with, the self-regulatory obligations of the Exchange. The Exchange believes the requirements in the BSTX LLC Agreement applicable to direct and indirect changes in control of the Company described above, the provisions of the Facility Agreement establishing the Exchange's regulatory control over the Company, as well as the voting limitation imposed on owners of the Company who also are BSTX Participants described above, are appropriate to help ensure that the Exchange is able to effectively carry out its self-regulatory responsibilities, including over the Company, and are consistent with the requirements of the Act.

In addition, each Member of BSTX and each Controlling Person thereof must give due regard to the preservation of the independence of the self-regulatory function of the Exchange and must not take any action that would interfere with the effectuation of decisions by the Exchange Board or interfere with the Exchange's ability to carry out its responsibilities under the Act.¹²¹ Each Member of BSTX and each Controlling Person thereof¹²² also is required to take such action as is necessary to ensure that its directors, officers and employees consent to giving due regard to the preservation of the independence of the self-regulatory function of the Exchange and to not taking any action that would interfere with the effectuation of decisions by the Exchange Board or interfere with the Exchange's ability to carry out its responsibilities under the Act to the extent related to the operation or administration of the Exchange or the Company.

The Exchange believes the provisions which are designed to help maintain the independence of BOX Exchange's regulatory function, are appropriate and consistent with the requirements of the Act, particularly with Section 6(b)(1), which requires, in part, an exchange to

be so organized and have the capacity to carry out the purposes of the Act.¹²³

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the Proposed Rule Change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Proceedings To Determine Whether To Approve or Disapprove SR-BOX-2021-14, as Modified by Amendment No. 1, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act¹²⁴ to determine whether the proposed rule change, as modified by Amendment No. 1, should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule change to inform the Commission's analysis of whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.

Pursuant to Section 19(b)(2)(B) of the Act,¹²⁵ the Commission is providing notice of the grounds for disapproval under consideration. As described above, the Exchange proposes to operate BSTX as a facility of the Exchange and adopt the proposed LLC Agreement and Form of Instrument of Accession as rules of the Exchange. Among other things, the Exchange proposes to establish BSTX as a facility of the Exchange that would operate a market for the trading of securities pursuant to rules established by a separate rule filing.¹²⁶ BSTX would be controlled jointly by BOX Digital, a subsidiary of BOX Holdings, which is the parent company of BOX Options, the Exchange's facility for the trading of

listed options, and tZERO, an indirect subsidiary of Overstock, a publicly traded company.¹²⁷ On September 16, 2021, the Exchange filed Amendment No. 1 to the proposed rule change. As stated above, the Commission has received no comment letters on the proposal.

The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the consistency of the proposed rule change, as modified by Amendment No. 1, with the Act, including, but not limited to, Section 6(b)(1) of the Act, which requires that a national securities exchange be so organized and have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the exchange;¹²⁸ Section 6(b)(3) of the Exchange Act, which requires that the rules of a national securities exchange assure a fair representation of its members in the selection of its directors and administration of its affairs and provide that one or more directors shall be representative of issuers and investors and not be associated with a member of the exchange, broker, or dealer;¹²⁹ and Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.¹³⁰

The Exchange states that BSTX will be jointly controlled by BOX Digital and tZERO, which would each own 50% of the voting class of equity of BSTX.¹³¹ According to the Exchange, it will enter into a Facility Agreement with BSTX pursuant to which the Exchange will regulate BSTX, and the Exchange's powers and authority under the Facility Agreement ensure that the Exchange has

¹²¹ See Article 4.6(a) of the Exchange LLC Agreement and Article 4.12(a) of the BSTX LLC Agreement.

¹²² See the LLC Agreement Section 7.4(g)(ii).

¹²³ 15 U.S.C. 78f(b)(1).

¹²⁴ 15 U.S.C. 78s(b)(2)(B).

¹²⁵ *Id.*

¹²⁶ See Amendment No. 1, *supra* note 6, at 4.

¹²⁷ See *id.* at 4, 8–11.

¹²⁸ 15 U.S.C. 78f(b)(1).

¹²⁹ 15 U.S.C. 78f(b)(3).

¹³⁰ 15 U.S.C. 78f(b)(5).

¹³¹ See Amendment No. 1, *supra* note 6, at 4, 6.

full regulatory control over BSTX, which is designed to prevent any owner of BSTX from exercising undue influence over the regulated activities of BSTX.¹³² The Exchange references, among other things, provisions limiting BSTX Participants to a maximum of 20% voting power at BSTX, provisions limiting Exchange Facility Participants to a maximum of 20% voting power at the Exchange, and ownership limits of 20% voting power and 40% economic ownership applicable to all owners of the Exchange, in stating its belief that the proposal is consistent with the Act.¹³³

In addition, the Exchange states that the Board of Directors of BSTX, which will be comprised of two directors appointed by each of BOX Digital and tZERO and one “Independent Director” that will be appointed by unanimous vote of the directors appointed by each of BOX Digital and tZERO,¹³⁴ will manage the development, operations, business and affairs of the Company without the need for any approval of the Members or any other person.¹³⁵ The Exchange believes that this proposed structure for the BSTX Board effectively limits any one Member to a maximum of 40% voting power of the Board.¹³⁶ The Exchange also states that the BSTX Board will include a Regulatory Director, appointed by the Exchange and who must be a member of the senior management of the regulation staff of the Exchange,¹³⁷ but this Regulatory Director will not have the power to vote on any action to be taken by the Board or any committee.¹³⁸ However, the proposed ownership structure, voting provisions, and board structure raise questions as to whether the proposal would protect against the undue

influence of any owner of BSTX over the affairs of BSTX and ensure that BSTX’s operation of the BSTX Market is consistent with and does not interfere with the Exchange’s regulatory responsibilities.¹³⁹

The Exchange states that the provisions in the proposed BSTX LLC Agreement are generally the same as the provisions of the BOX Options LLC Agreement or the BOX Holdings LLC Agreement,¹⁴⁰ that replicating those provisions may foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities,¹⁴¹ and that the structure of the BSTX will promote just and equitable principles of trade, and, in general, protect investors and the public interest, consistent with Section 6(b)(5) of the Act.¹⁴² But the Exchange also states that BSTX does not have the same ownership as BOX Options or BOX Holdings,¹⁴³ and it is unclear how, given the differences between the proposed ownership and proposed governance structure of BSTX compared to those of BOX Options and BOX Holdings, the proposed provisions would ensure that the Exchange and the Commission are able to carry out their regulatory obligations with respect to BSTX.

The Commission believes there are questions as to whether the Exchange’s proposed governance structure is consistent with Section 6(b)(1) of the Act, and, in particular, the requirements that the Exchange be so organized and has the capacity to carry out the purposes of the Act; and Section 6(b)(5) of the Act, and in particular the requirement that the rules of an exchange be designed to promote just and equitable principles of trade; and, in general, to protect investors and the public interest. The Commission also believes there are questions as to whether the Exchange’s proposal is consistent with Section 6(b)(3) of the Act, and in particular the requirement that the rules of a national securities exchange assure a fair representation of its members in the selection of its

directors and administration of its affairs.¹⁴⁴

Under the Commission’s Rules of Practice, the “burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the [SRO] that proposed the rule change.”¹⁴⁵ The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,¹⁴⁶ and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and the applicable rules and regulations.¹⁴⁷

For these reasons, the Commission believes it is appropriate to institute proceedings pursuant to Section 19(b)(2)(B) of the Act to determine whether the proposal should be approved or disapproved.

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal, as modified by Amendment No. 1, is consistent with Sections 6(b)(1),¹⁴⁸ 6(b)(3),¹⁴⁹ and 6(b)(5) of the Act¹⁵⁰ or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act,¹⁵¹ any request for an opportunity to make an oral presentation.¹⁵²

¹⁴⁴ See *id.* at 57–59 (discussing, among other things, the Exchange’s rules that would govern the inclusion of a Participant Director, selected from among the officers, directors and employees of BSTX Participants, on the Exchange’s Board of Directors).

¹⁴⁵ 17 CFR 201.700(b)(3).

¹⁴⁶ See *id.*

¹⁴⁷ See *id.*

¹⁴⁸ 15 U.S.C. 78f(b)(1).

¹⁴⁹ 15 U.S.C. 78f(b)(3).

¹⁵⁰ 15 U.S.C. 78f(b)(5).

¹⁵¹ 17 CFR 240.19b–4.

¹⁵² Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Public Law

¹³² See *id.* at 5. The Exchange also states that certain provisions in the BSTX LLC Agreement are the same as provisions in the BOX Options LLC Agreement and that such provisions ensure that the Exchange has full regulatory control over BSTX, which is designed to prevent any owner of BSTX from exercising undue influence over the regulated activities of the Company. See *id.* at 18–20.

¹³³ See *id.* at 60–62.

¹³⁴ See *id.* at 20.

¹³⁵ See *id.* at 18–19. The Exchange states that the purpose of the Independent Director is to avoid either BOX Digital or tZERO from controlling or creating deadlock on the Board. See *id.* at 21.

¹³⁶ See *id.*

¹³⁷ See *id.* at 20.

¹³⁸ See *id.* at 22. The Exchange states that the proposed structure for the BSTX Board of Directors differs from that of BOX Holdings because the ownership of BSTX differs from that of BOX Holdings, which has more than two owners of its voting class of equity and uses a tiered system in which board voting is based on ownership in BOX Holdings, but that the inclusion of a Regulatory Director selected by the Exchange on the Board is identical to the longstanding practice at the Exchange’s other facility, BOX Options. See *id.* at 20–21.

¹³⁹ There are also questions about whether the Exchange will have the ability to obtain the information necessary to ascertain whether potential direct or indirect owners of BSTX are required to provide notice to BSTX or to take other actions, such as executing an amendment to the LLC Agreement upon establishing a Controlling Interest, and whether the Exchange and the Commission will have the capacity to monitor compliance with the proposed provisions related to changes in ownership and control.

¹⁴⁰ See *id.* at 6.

¹⁴¹ See *id.* at 7.

¹⁴² See *id.* at 16.

¹⁴³ See *id.*

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal, as modified by Amendment No. 1, should be approved or disapproved by October 18, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by November 1, 2021.

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in Amendment No. 1,¹⁵³ in addition to any other comments they may wish to submit about the proposed rule change.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BOX-2021-14 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-BOX-2021-14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the

filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BOX-2021-14 and should be submitted by October 18, 2021. Rebuttal comments should be submitted by November 1, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵⁴

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-20816 Filed 9-24-21; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF STATE

[Public Notice: 11549]

Update on Report to Congress Pursuant to Section 353(d)(1)(A) of the United States-Northern Triangle Enhanced Engagement Act

ACTION: Notice of report.

SUMMARY: This document provides an update to the State Department's report to Congress regarding foreign persons who have knowingly engaged in actions that undermine democratic processes or institutions, significant corruption, or obstruction of such corruption in El Salvador, Guatemala, and Honduras pursuant to Section 353(b) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2021.

SUPPLEMENTARY INFORMATION: Update to Report to Congress on Foreign Persons who have Knowingly Engaged in Actions that Undermine Democratic Processes or Institutions, Significant Corruption, or Obstruction of Such Corruption in El Salvador, Guatemala, and Honduras Section 353(b) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2021 (Div. FF, Pub. L. 116-260)

Consistent with Section 353(b) of the United States-Northern Triangle Enhanced Engagement Act (Div. FF, Pub. L. 116-260) (the Act), this report update is being submitted to the House Foreign Affairs Committee, Senate Foreign Relations Committee, House

Committee on the Judiciary, and the Senate Committee on the Judiciary.

Section 353(b) requires the submission of a report that identifies the following persons in El Salvador, Guatemala, and Honduras: (1) Foreign persons determined to have knowingly engaged in actions that undermine democratic processes or institutions; (2) foreign persons determined to have knowingly engaged in significant corruption; and (3) foreign persons determined to have knowingly engaged in obstruction of investigations into such acts of corruption, including the following: Corruption related to government contracts; bribery and extortion; the facilitation or transfer of the proceeds of corruption, including through money laundering; and acts of violence, harassment, or intimidation directed at governmental and nongovernmental corruption investigators.

Under Section 353, foreign persons identified under the Act are generally ineligible for visas and admission to the United States. Section 353 further requires that foreign persons identified under the Act shall have their visas revoked immediately and any other valid visa or entry documentation cancelled. Consistent with Section 353(g), this report update will be published in the **Federal Register**.

This report update includes individuals for whom the Department is aware of credible information or allegations of the conduct at issue, from media reporting and other sources. The Department will continue to review the individuals listed in the report and consider all available tools to deter and disrupt corrupt, undemocratic activity in El Salvador, Guatemala, and Honduras. The Department also continues to actively review additional credible information and allegations concerning corruption and to utilize all applicable authorities, as appropriate, to ensure corrupt officials are denied safe haven in the United States.

El Salvador

Elsy Dueñas De Aviles, Oscar Alberto López Jerez, Hector Nahun Martinez Garcia, Jose Angel Perez Chacon, and Luis Javier Suárez Magaña, current Magistrates of the Constitutional Chamber of the Supreme Court, undermined democratic processes or institutions by accepting direct appointments to the Chamber by the Legislative Assembly, in an unusual process in apparent contravention of the processes set out at Article 186 of the Constitution, which requires the selection of such Magistrates from a list of candidates drafted by the National

94-29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

¹⁵³ See Amendment No. 1, *supra* note 6.

¹⁵⁴ 17 CFR 200.30-3(a)(57).

Council of the Judiciary. The previous five Magistrates were abruptly removed without legitimate cause following the May 1 seating of the newly elected Legislative Assembly. After being installed, the new Magistrates declared their installation by the Legislative Assembly to have been constitutional. The Magistrates subsequently also undermined democratic processes or institutions by approving a controversial interpretation of the Constitution authorizing re-election of the President despite an express prohibition in the Constitution forbidding consecutive terms of the Presidency.

Guatemala

Angel Arnoldo Pineda Avila, current Secretary General of Guatemala's Public Ministry (MP), obstructed investigations into acts of corruption by interfering in anti-corruption probes. The MP has opened a probe into allegations that Pineda interfered in an anti-corruption investigation. Pineda is alleged to have tipped off investigative targets about cases being built against them. In one instance, Pineda reportedly leaked confidential information to the director of Guatemala's Victim Institute about an ongoing investigation into more than 100 falsified personnel contracts at the institution.

Maria Consuelo Porras Argueta De Porres, current Attorney General of Guatemala, obstructed investigations into acts of corruption by interfering with criminal investigations in order to protect political allies and gain personal political favor. Porras' pattern of obstruction included ordering prosecutors in the MP to ignore cases based on political considerations and actively undermining investigations into political allies carried out by the Special Prosecutor Against Impunity, including by improperly firing its lead prosecutor, Juan Francisco Sandoval, and transferring and firing prosecutors who investigate the current administration or the MP itself.

Dated: September 13, 2021.

Wendy R. Sherman,

Deputy Secretary of State.

[FR Doc. 2021-20821 Filed 9-24-21; 8:45 am]

BILLING CODE 4710-29-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA-2021-0006-N-12]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, this notice announces that FRA is forwarding the Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and comment. The ICR describes the information collection and its expected burden. On June 29, 2021, FRA published a notice providing a 60-day period for public comment on the ICR.

DATES: Interested persons are invited to submit comments on or before October 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed ICR should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find the particular ICR by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Ms. Hodan Wells, Information Collection Clearance Officer at email: Hodan.Wells@dot.gov or telephone: (202) 493-0440.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501-3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. See 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. On June 29, 2021, FRA published a 60-day notice in the **Federal Register** soliciting comment on the ICR for which it is now seeking OMB approval. See 86 FR 34303. FRA received no comments in response to this 60-day notice.

Before OMB decides whether to approve the proposed collection of information, it must provide 30 days for public comment. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)-(c); 5 CFR

1320.10(b); see also 60 FR 44978, 44983 (Aug. 29, 1995). OMB believes the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983 (Aug. 29, 1995). Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

Comments are invited on the following ICR regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the information will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Hours of Service Regulations.

OMB Control Number: 2130-0005.

Abstract: FRA's hours of service recordkeeping regulations (49 CFR part 228), amended as mandated by the Rail Safety Improvement Act of 2008, include substantive hours of service requirements for train employees (*i.e.*, locomotive engineers and conductors) providing commuter and intercity rail passenger transportation (*e.g.*, maximum on-duty periods, minimum off-duty periods, and other limitations). The regulations also require railroads to evaluate passenger train employee work schedules for risk of employee fatigue and implement measures to mitigate the risk, and to submit to FRA for approval certain schedules and mitigation plans. Finally, the regulations include recordkeeping and reporting provisions requiring railroads to keep hours of service records, and report excessive service, for train employees, signal employees, and dispatching service employees on both freight and passenger railroads.

FRA uses the information collected to verify that railroads do not require or allow their employees to exceed maximum on-duty periods, and ensure that they abide by minimum off-duty periods, and adhere to other limitations in this regulation, to enhance rail safety and reduce the risk of accidents/

incidents caused, or contributed to, by train employee fatigue.

Type of Request: Extension without change (with changes in estimates) of a currently approved collection.

Affected Public: Businesses (railroads and signal contractors).

Form(s): FRA F 6180.3.

Respondent Universe: 796 railroads, signal contractors and subcontractors.

Frequency of Submission: On occasion.

Total Estimated Annual Responses: 18,660,400.

Total Estimated Annual Burden: 1,283,507 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: \$99,404,352.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that a respondent is not required to respond to, conduct, or sponsor a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Brett A. Jortland,

Acting Chief Counsel.

[FR Doc. 2021–20854 Filed 9–24–21; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0223]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: SEA HAG (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0223 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD–2021–0223 and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2021–0223, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–459, Washington, DC 20590. Telephone 202–366–5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel SEA HAG is:

—*Intended Commercial Use of Vessel:* “SCUBA diving and sport fishing charters.”

—*Geographic Region Including Base of Operations:* “New Jersey, Delaware, New York, Connecticut, Rhode Island, New Hampshire, Massachusetts, Maine, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida” (Base of Operations: Barnegat Light, NJ)

—*Vessel Length and Type:* 29.0' Motor (crew boat)

The complete application is available for review identified in the DOT docket as MARAD 2021–0223 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part

388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD–2021–0223 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be

followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20863 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0217]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: SALMON PRINCESS (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.
ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number

MARAD-2021-0217 by any one of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Search MARAD-2021-0217 and follow the instructions for submitting comments.

- **Mail or Hand Delivery:** Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0217, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel SALMON PRINCESS is:

—**Intended Commercial Use of Vessel:**

“Day outings for near coastal birdwatching, sightseeing, harbor tours, and recreational fishing for 12 passengers as limited by this waiver. A U.S. Coast Guard COI is intended to be obtained to haul more than 6 passengers.”

—**Geographic Region Including Base of Operations:** “Washington, Oregon, California” (Base of Operations: Westport, WA)

—**Vessel Length and Type:** 42.0' Motor

The complete application is available for review identified in the DOT docket as MARAD 2021-0217 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag

vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0217 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA)

request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20872 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0224]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: SHANNON (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0224 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD-2021-0224 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0224, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION:

As described in the application, the intended service of the vessel SHANNON is:

—*Intended Commercial Use of Vessel:*

“For commercial charter specializing in burials at sea in Marina del Rey and Long Beach.”

—*Geographic Region Including Base of Operations:* “California” (Base of Operations: Marina del Rey, CA)

—*Vessel Length and Type:* 70.0' Motor.

The complete application is available for review identified in the DOT docket as MARAD 2021-0224 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel

in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0224 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is

ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

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By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20864 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0226]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: HILINA'I (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.
ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0226 by any one of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Search MARAD-2021-0226 and follow the instructions for submitting comments.

- **Mail or Hand Delivery:** Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0226, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel HILINA'I is:

- Intended Commercial Use of Vessel:* "High-end private charters, including but not limited to snorkel trips and sunset trips."
- Geographic Region Including Base of Operations:* "Hawaii" (Base of Operations: Honolulu, HI)
- Vessel Length and Type:* 43.0' Motor Catamaran

The complete application is available for review identified in the DOT docket as MARAD 2021-0226 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or

a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0226 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading "Contains Confidential Commercial Information" or "Contains CCI" and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

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By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20861 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0213]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: 05 (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0213 by any one of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Search MARAD-2021-0213 and follow the instructions for submitting comments.

- **Mail or Hand Delivery:** Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0213, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel 05 is:

—**Intended Commercial Use of Vessel:** “Sleep overnight on a catamaran under the stars.”

—**Geographic Region Including Base of Operations:** “Hawaii” (Base of Operations: Honolulu, HI)

—**Vessel Length and Type:** 43.0' Sail (Catamaran)

The complete application is available for review identified in the DOT docket as MARAD 2021-0213 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the

commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0213 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

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By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20865 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0221]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: MIDNIGHT FANCY (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.
ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0221 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD-2021-0221 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The

Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0221, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel MIDNIGHT FANCY is:

—*Intended Commercial Use of Vessel:* “Looking to take people on pleasure cruises for recreational and leisure purposes.”

—*Geographic Region Including Base of Operations:* “Florida—East and Gulf coasts” (Base of Operations: Cocoa Beach, FL)

—*Vessel Length and Type:* 52.5' Motor

The complete application is available for review identified in the DOT docket as MARAD 2021-0221 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given

in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0221 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as

described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20876 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0215]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: GLADIATOR (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.
ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0215 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD-2021-0215 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0215,

1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel GLADIATOR is:

—*Intended Commercial Use of Vessel:* “Passenger day cruises around San Diego harbor; Sportfishing charters.”

—*Geographic Region Including Base of Operations:* “California, Oregon” (Base of Operations: San Diego, CA)

—*Vessel Length and Type:* 72.0' Motor

The complete application is available for review identified in the DOT docket as MARAD 2021-0215 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0215 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible

through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

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By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20867 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0219]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: FULL SEND (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.
ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0219 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD-2021-0219 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0219, 1200 New Jersey Avenue SE, West

Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel FULL SEND is:

—*Intended Commercial Use of Vessel:*

“Coastal cruising in the waters of Southern California.”

—*Geographic Region Including Base of Operations:* “California” (Base of Operations: Marina del Rey, CA).

—*Vessel Length and Type:* 63.0' Motor

The complete application is available for review identified in the DOT docket as MARAD 2021-0219 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the

instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0219 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of

names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20874 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0222]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: SQUIRT (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.
ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0222 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD-2021-0222 and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0222, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you

include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel SQUIRT is:

- Intended Commercial Use of Vessel:* “Sightseeing, whale watching, sailing lessons, vessel handling instruction.”
- Geographic Region Including Base of Operations:* “California” (Base of Operations: Channel Islands, CA)
- Vessel Length and Type:* 37.8’ Sail

The complete application is available for review identified in the DOT docket as MARAD 2021-0222 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel’s coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter’s interest in the application, and address the eligibility criteria given in section 388.4 of MARAD’s regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected

on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0222 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department’s FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20862 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0220]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: CHANCEUSE (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.
ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0220 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD-2021-0220 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0220, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you

if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel CHANCEUSE is:

—*Intended Commercial Use of Vessel:*

“Day charters and term charters with or without crew for up to 6 passengers.”

—*Geographic Region Including Base of Operations:* “Maryland” (Base of Operations: Annapolis, MD)

—*Vessel Length and Type:* 45.0' Sail

The complete application is available for review identified in the DOT docket as MARAD 2021-0220 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise

comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0220 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20875 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0218]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: MARIAH (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0218 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD-2021-0218 and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0218, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel MARIAH is:

—*Intended Commercial Use of Vessel:* “Sailing tours.”

—*Geographic Region Including Base of Operations:* “Hawaii” (Base of Operations: Honolulu, HI)

—*Vessel Length and Type:* 38.0' Sail

The complete application is available for review identified in the DOT docket as MARAD 2021-0218 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0218 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20873 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0225]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: MIA (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0225 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD-2021-0225 and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0225, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel MIA is:

—*Intended Commercial Use of Vessel:* “Carrying of passengers—luxury motor yacht for hire.”

—*Geographic Region Including Base of Operations:* “Florida, Georgia” (Base of Operations: Key West, FL)

—*Vessel Length and Type:* 86.0' Motor

The complete application is available for review identified in the DOT docket as MARAD 2021-0225 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0225 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20868 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0214]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: HIGH YIELD (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0214 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD-2021-0214 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0214, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel HIGH YIELD is:

- Intended Commercial Use of Vessel:* “The vessel will be used for premium limited load Sportfishing charter.”
- Geographic Region Including Base of Operations:* “California” (Base of Operations: San Diego, CA)
- Vessel Length and Type:* 47.0' Motor

The complete application is available for review identified in the DOT docket as MARAD 2021-0214 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0214 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20866 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0027]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: BLUE SKIES (Motor); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0027 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD-2021-0027 and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0027, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel BLUE SKIES is:

—*Intended Commercial Use of Vessel:*

“6 passengers maximum excursion vessel for OUPV use only.”

—*Geographic Region Including Base of Operations:* “California” (Base of Operations: Richmond, CA)

—*Vessel Length and Type:* 35.0' Motor.

The complete application is available for review identified in the DOT docket as MARAD 2021-0027 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0027 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20869 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2021-0216]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: BRAVADO (Sail); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 27, 2021.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD-2021-0216 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Search MARAD-2021-0216 and follow the instructions for submitting comments.

- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD-2021-0216, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and

specific docket number. All comments received will be posted without change to the docket at www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT:

James Mead, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-459, Washington, DC 20590. Telephone 202-366-5723, Email James.Mead@dot.gov.

SUPPLEMENTARY INFORMATION: As

described in the application, the intended service of the vessel BRAVADO is:

—*Intended Commercial Use of Vessel:* “Sailing charters.”

—*Geographic Region Including Base of Operations:* “North Carolina” (Base of Operations: Beaufort, NC)

—*Vessel Length and Type:* 45.0' Sail

The complete application is available for review identified in the DOT docket as MARAD 2021-0216 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at <http://www.regulations.gov>, keyword search MARAD-2021-0216 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to SmallVessels@dot.gov. Include in the email subject heading “Contains Confidential Commercial Information” or “Contains CCI” and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

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, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021-20871 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Clarification of Departmental Position on American Airlines—JetBlue Airways Northeast Alliance Joint Venture

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Clarification notice.

SUMMARY: By this notice, the U.S. Department of Transportation (DOT or Department) clarifies its position on the American Airlines (American) and JetBlue Airways (JetBlue) Northeast Alliance (NEA) joint venture agreements and the January 10, 2021 agreement between and among DOT, JetBlue and American (DOT Agreement) terminating the Department's review of the NEA, following the September 21, 2021 announcement of antitrust litigation by the U.S. Department of Justice (DOJ). The Department will work closely with DOJ should it seek data and documents that will help in the resolution of DOJ's action. The DOT Agreement remains in effect during the pendency of the DOJ litigation. The Department retains independent statutory authority to prohibit unfair methods of competition in air transportation to further its statutory objectives to prevent predatory or anticompetitive practices and to avoid unreasonable industry concentration.¹ However, the Department intends to defer to DOJ, as the primary enforcer of Federal antitrust laws, to resolve the antitrust concerns that DOJ has identified with respect to the NEA. The Department also intends to stay the proceedings in a Spirit Airlines, Inc. (Spirit) formal complaint against the NEA's implementation while the DOJ action is pending. The Department will assess its next steps, if any, relating to the Spirit complaint and the NEA at the conclusion of the DOJ litigation.

DATES: September 27, 2021.

FOR FURTHER INFORMATION CONTACT:

Blane A. Workie or Ryan Patanaphan, Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, at 202-366-9342 or by email at

blane.workie@dot.gov or *ryan.patanaphan@dot.gov*, or Todd Homan, Director, Office of Aviation Analysis, 1200 New Jersey Ave. SE, Washington, DC 20590, 202-366-5903, *Todd.Homan@dot.gov* (email).

SUPPLEMENTARY INFORMATION:

Background

In 2020, American and JetBlue submitted to the Department joint venture agreements concerning the NEA, which covered code-sharing, frequent flyer, interline, revenue sharing, and asset sharing. The agreements and supporting documentation were submitted to the Department under 49 U.S.C. 41720, which requires that major air carriers submit joint venture agreements to the Department at least 30 days before the agreements take effect. Section 41720 permits the Department to extend the 30-day period up to an additional 150 days for joint venture agreements involving code-sharing and 60 days for other types of joint venture agreements.

Consistent with past precedent, the Department chose to conduct the review of the NEA informally and without establishing a docketed proceeding.² As permitted by 49 U.S.C. 41720, the Department extended its review and the waiting period for the NEA to November 19, 2020, via a Federal Notice issued on August 20, 2020.³ In the notice, the Department explained that it would consult with DOJ during its review, and that its focus was on whether the NEA would likely reduce competition and create the potential for collusion or other restrictions on price and service levels in markets where the carriers compete.

Section 41720 does not provide the Department the authority to approve or disapprove agreements submitted for review under that section; rather, the section gives the Department a limited period of time to review the agreements before such agreements may take effect. DOJ, which is responsible for enforcing Federal antitrust laws and has also been conducting its own review of the NEA, had not concluded its investigation at the time DOT's review period ended and DOT entered in the DOT Agreement with American and JetBlue on January 10, 2021. Section 41720 does not require

² See, e.g., 67 FR 50,745 (Aug. 5, 2002) (United Air Lines and US Airways) and 67 FR 69,804 (Nov. 19, 2002) (Delta Air Lines, Northwest Airlines, and Continental Airlines). Both agreements were subject to an informal, non-docketed review, although third parties were given the opportunity to submit comments on the agreements due to public interest concerns, subject to access restrictions designed to ensure that confidential business information did not become public.

³ 85 FR 51,552 (Aug. 20, 2020).

DOJ to adhere to a particular timeframe for its review. If an alliance agreement appears to be problematic, the Department and DOJ have separate authority to address anticompetitive conduct. As the Department's time-limited review of the NEA was concluding, it was aware that DOJ was continuing its detailed review and identifying and examining concerns on the impact on competition.

In this context, DOT's review of the NEA under section 41720 was not designed to approve or disapprove the alliance. During the Department's review, American and JetBlue entered into negotiations with DOT. These negotiations culminated in the DOT Agreement with American and JetBlue on January 10, 2021, in which the carriers agreed to take actions to address several Departmental concerns about anticompetitive harms arising out of the NEA.⁴ The DOT Agreement did not address all of the Department's concerns resulting from the NEA's impacts on competition, but instead sought concessions from the carriers that were intended to mitigate some of the anticompetitive harm while providing a means for monitoring the NEA's implementation.

For example, the DOT Agreement required upfront slot divestitures of six slot-pairs at Ronald Reagan Washington National Airport (DCA), seven slot-pairs at John F. Kennedy International Airport (JFK), and a conditional divestiture of up to ten additional slots at JFK if the carriers failed to meet capacity growth targets in New York City (limited to JFK and LaGuardia Airports). In the case of the DCA slot-pairs, a perpetual-lease arrangement provided for the divested slots to be reacquired by the carriers in the event that the NEA is discontinued. The carriers also agreed to periodically report to DOT capacity figures, route changes, and slot and gate utilization metrics. The carriers agreed to adhere to antitrust protocols to limit the type of communications between them, as well as other commitments.

The DOT Agreement does not expand or restrict the Department's existing statutory and regulatory authorities, including the ability to investigate and prohibit potentially unfair, deceptive, or exclusionary practices.⁵ The parties to

⁴ The agreement can be found at <https://www.transportation.gov/sites/dot.gov/files/2021-01/Agreement%20terminating%20review%20DOT-AA-B6%20with%20appendix%2011021%20website.pdf>.

⁵ Section 7 of the DOT Agreement specifies that "[n]othing in this Agreement shall expand or restrict DOT's existing statutory and regulatory authorities, or at any time prohibit or limit DOT

Continued

¹ 49 U.S.C. 40101.

the DOT Agreement recognized that the alliance was still subject to the antitrust laws, that DOJ was continuing its review, and that DOT retained its authority to remedy any competitive harm.

Spirit Airlines Formal Complaint

On January 7, 2021, prior to execution and public release of the DOT Agreement, Spirit filed a formal complaint with DOT that was docketed in DOT-OST-2021-0001. In its complaint, Spirit requested an on-the-record investigation of the NEA to determine whether the NEA's implementation would constitute an unfair method of competition in violation of 49 U.S.C. 41712(a).⁶ Spirit also asserted that insufficient information about the NEA was made public during the Department's review, and that the remedies agreed to in the DOT Agreement were insufficient to address anticompetitive concerns.

Several entities, including other airlines, an airline association, a consumer advocacy organization, and a non-profit organization focused on competition, submitted comments supporting various aspects of Spirit's complaint.⁷ Those comments were filed after the public release of the DOT Agreement. American and JetBlue filed answers opposing Spirit's complaint.

DOJ Litigation

On September 21, 2021, after completing an extended review of the NEA, DOJ announced its determination that the NEA violates the antitrust laws

and that the agency has initiated action to enjoin the agreements. DOJ has shared with the Department its significant concerns with respect to the effect of the NEA on competition. The Department notes that the DOT Agreement does not, nor was it intended to, wholly address these concerns. The Department will work closely with DOJ should it seek data and documents that will help in the resolution of DOJ's action.

Because of the DOJ action, and to avoid duplicative or inconsistent proceedings, DOT is separately staying the proceedings in the Spirit formal complaint while the DOJ action is unresolved. Although the DOT Agreement remains in effect, the Department will continue coordinating with DOJ. The Department notes its own statutory authority to investigate and prohibit anticompetitive conduct if the situation warrants. However, the Department intends to defer to DOJ, as the primary enforcer of Federal antitrust laws, to resolve antitrust concerns with respect to the NEA. The Department believes that it would be inefficient and unhelpful to have two concurrent proceedings and therefore intends to defer any independent action until the DOJ antitrust litigation has concluded.

Issued this 21st Day of September, 2021, in Washington, DC.

John E. Putnam,

Acting General Counsel.

[FR Doc. 2021-20849 Filed 9-24-21; 8:45 am]

BILLING CODE 4910-9X-X

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing updates to the identifying information of one or more persons currently included in the SDN List. All property and interests in property subject to U.S. jurisdiction of these persons remain blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See Supplementary Information section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202-622-2480; Associate Director for Global Targeting, tel.: 202-622-2420; Assistant Director for Licensing, tel.:

202-622-2480; Assistant Director for Regulatory Affairs, tel.: 202-622-4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202-622-2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (www.treasury.gov/ofac).

Notice of OFAC Actions

On September 22, 2021, OFAC updated the entries on the SDN List for the following persons, whose property and interests in property subject to U.S. jurisdiction continue to be blocked under the relevant sanctions authorities listed below.

Individuals

1. BARAKZAI ANSARI, Haji Abdullah (a.k.a. ANSARI, Haji Abdullah; a.k.a. BARAKZAI, Haji Abdullah), c/o NEW ANSARI MONEY EXCHANGE, Afghanistan; National ID No. 10331 (Afghanistan) (individual) [SDNTK].

-to- BARAKZAI ANSARI, Haji Abdullah (a.k.a. ANSARI, Haji Abdullah; a.k.a. BARAKZAI, Haji Abdullah), Afghanistan; DOB 1962; nationality Afghanistan; Gender Male; National ID No. 10331 (Afghanistan) (individual) [SDNTK] (Linked To: NEW ANSARI MONEY EXCHANGE).

Designated pursuant to one or more of the criteria under the Foreign Narcotics Kingpin Designation Act (Kingpin Act), 21 U.S.C. 1904(b).

2. GHANI, Mohammad Nadeem (a.k.a. GHANI, Mohamed Nadim), c/o ZULEKHA GENERAL TRADING LLC, Ajman, United Arab Emirates; United Kingdom; citizen United Kingdom; Passport 093055372 (United Kingdom) (individual) [SDNTK].

-to- GHANI, Mohammad Nadeem (a.k.a. GHANI, Mohamed Nadim), United Kingdom; DOB Feb 1968; nationality United Kingdom; citizen United Kingdom; Gender Male; Passport 093055372 (United Kingdom) (individual) [SDNTK].

Designated pursuant to one or more of the criteria under the Kingpin Act.

3. KHALAF, Fuad Mohamed (a.k.a. KALAF, Fuad Mohamed; a.k.a. KALAF, Fuad Mohammed; a.k.a. KHALAF, Fuad; a.k.a. KHALIF, Fuad Mohamed; a.k.a. QALAF, Fuad Mohamed; a.k.a. SHANGOLE, Fuad; a.k.a. SHONGALE, Fouad; a.k.a.

from exercising those authorities, including but not limited to investigation and enforcement regarding: (1) Potentially unfair or deceptive practices; (2) potentially exclusionary practices; [or] (3) acquisition or operation of additional slots or gates not currently held by American or JetBlue."

⁶ The Department's authority to address competition concerns is separate and distinct from that of DOJ, covering a different scope of anticompetitive conduct than DOJ's authority. Under 49 U.S.C. 41712, the Department has authority to investigate and decide whether a carrier has been or is engaging in an unfair method of competition in air transportation. The Department prohibits anticompetitive conduct that (1) violates the antitrust laws, (2) is not yet serious enough to violate the antitrust laws but may well do so if left unchecked, or (3) although not a violation of the letter of the antitrust laws, is close to a violation or is contrary to their spirit. See, e.g., *ASTA v. United et al.*, DOT Order 2002-9-2 (Sep. 4, 2002), citing *E.I. Du Pont de Nemours and Co. v. Federal Trade Commission*, 729 F.2d 128, 136-137 (2d Cir. 1984). *E.I. Du Pont de Nemours* interpreted the Federal Trade Commission's authority under 15 U.S.C. 45, upon which 49 U.S.C. 41712 is based.

⁷ The organizations included the National Air Carrier Association, Southwest Airlines, United Airlines, Travelers United, the American Antitrust Institute, Airports Council International—North America, and the Service Employees International Union.

SHONGALE, Fuad; a.k.a. SHONGOLE, Fuad; a.k.a. SHONGOLE, Fuad Muhammad Khalaf; a.k.a. SONGALE, Fuad), Mogadishu, Somalia; nationality Somalia; alt. nationality Sweden (individual) [SOMALIA].

-to-
KHALAF, Fuad Mohamed (a.k.a. KALAF, Fuad Mohamed; a.k.a. KALAF, Fuad Mohammed; a.k.a. KHALAF, Fuad Mohamed; a.k.a. KHALIF, Fuad Mohammed; a.k.a. QALAF, Fuad Mohamed; a.k.a. SHANGOLE, Fuad; a.k.a. SHONGALE, Fouad; a.k.a. SHONGALE, Fuad; a.k.a. SHONGOLE, Fuad; a.k.a. SHONGOLE, Fuad Muhammad Khalaf; a.k.a. SONGALE, Fuad), Mogadishu, Somalia; DOB 28 Mar 1965; alt. DOB 28 May 1965; POB Somalia; nationality Somalia; alt. nationality Sweden; Gender Male (individual) [SOMALIA].

Designated pursuant to one or more of the criteria set forth in Executive Order 13536 of April 12, 2010, "Blocking Property of Certain Persons Contributing to the Conflict in Somalia."

4. OCHOA GUISAO, Walter, Colombia; POB Colombia; nationality Colombia; citizen Colombia; Cedula No. 10179825 (Colombia) (individual) [SDNTK].

-to-
OCHOA GUISAO, Walter, Colombia; DOB 23 Dec 1972; POB Santa Fe, Colombia; nationality Colombia; citizen Colombia; Gender Male; Cedula No. 10179825 (Colombia) (individual) [SDNTK].

Designated pursuant to one or more of the criteria under the Kingpin Act.

5. RANGEL SILVA, Henry de Jesus, Caracas, Venezuela; Cedula No. 5.764.952 (Venezuela); alt. Cedula No. V-5.764.952 (Venezuela); Director, Venezuelan Directorate of Intelligence and Prevention Services ("DISIP") (individual) [SDNTK].

-to-
RANGEL SILVA, Henry de Jesus, Caracas, Venezuela; DOB 28 Aug 1961; nationality Venezuela; Gender Male; Cedula No. 5.764.952 (Venezuela); alt. Cedula No. V-5.764.952 (Venezuela); Director, Venezuelan Directorate of Intelligence and Prevention Services ("DISIP") (individual) [SDNTK].

Designated pursuant to one or more of the criteria under the Kingpin Act.

6. RODRIGUEZ CHACIN, Ramon Emilio, Venezuela; Cedula No. 3169119 (Venezuela); Former Minister of Interior and Justice of Venezuela (individual) [SDNTK].

-to-
RODRIGUEZ CHACIN, Ramon Emilio, Venezuela; DOB 25 Sep 1949; nationality Venezuela; Gender Male; Cedula No. 3169119 (Venezuela); Passport 045723759 (Venezuela); Former Minister of Interior and Justice of Venezuela (individual) [SDNTK].

Designated pursuant to one or more of the criteria under the Kingpin Act.

7. TORRES MARTINEZ, Camilo, c/o REPUESTOS EL NATO Y CIA LTDA., Medellin, Colombia; c/o MI CARRO E.U., Medellin, Colombia; c/o AGROPECUARIA HATO SANTA MARIA LTDA., Medellin, Colombia; Colombia; POB Colombia; nationality Colombia; citizen Colombia; Cedula No. 71984381 (Colombia) (individual) [SDNTK].

-to-
TORRES MARTINEZ, Camilo, Colombia; DOB 31 Oct 1975; POB Unguia, Choco, Colombia; nationality Colombia; citizen Colombia; Gender Male; Cedula No. 71984381 (Colombia) (individual) [SDNTK].

Designated pursuant to one or more of the criteria under the Kingpin Act.

Entity

1. ZULEKHA GENERAL TRADING LLC (a.k.a. ZULEIKHA GENERAL TRADING; a.k.a. ZULIKHA GENERAL TRADING), P.O. Box 5456, Ajman, United Arab Emirates; C.R. No. 32035 (United Arab Emirates) [SDNTK].

-to-
ZULEKHA GENERAL TRADING LLC (a.k.a. ZULEIKHA GENERAL TRADING; a.k.a. ZULIKHA GENERAL TRADING), P.O. Box 5456, Ajman, United Arab Emirates; C.R. No. 32035 (United Arab Emirates) [SDNTK] (Linked To: GHANI, Mohammad Nadeem).

Designated pursuant to one or more of the criteria under the Kingpin Act.

Dated: September 22, 2021.

Bradley T. Smith,

Acting Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2021-20947 Filed 9-24-21; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets

Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date.

FOR FURTHER INFORMATION CONTACT:

OFAC: Andrea Gacki, Director, tel.: 202-622-2490; Associate Director for Global Targeting, tel.: 202-622-2420; Assistant Director for Licensing, tel.: 202-622-2480; Assistant Director for Regulatory Affairs, tel.: 202-622-4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202-622-2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (www.treasury.gov/ofac).

Notice of OFAC Action

On September 22, 2021, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individuals

1. MARTINEZ RENTERIA, Gilberto (a.k.a. "EL 50"; a.k.a. "EL CINCUENTA"; a.k.a. "EL GILIO"), Mexico; DOB 14 May 1987; POB Nogales, Sonora, Mexico; nationality Mexico; Gender Male; C.U.R.P. MARG70514HSRRNL00 (Mexico) (individual) [SDNTK]. Designated pursuant to section 805(b)(2) of the Foreign Narcotics Kingpin Designation Act (Kingpin Act), 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of, Sergio VALENZUELA VALENZUELA.

2. GONZALEZ HIGUERA, Jaime Humberto (a.k.a. "EL TUNCO"; a.k.a. "TUNCO"), Mexico; DOB 25 Mar 1986; POB Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. GOHJ860325HSLNGM02 (Mexico) (individual) [SDNTK]. Designated pursuant to section 805(b)(2) of the Foreign Narcotics Kingpin Designation Act (Kingpin Act), 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of, Sergio VALENZUELA VALENZUELA.

3. ROMAN FIGUEROA, Jorge Damian (a.k.a. "EL SOLDADO"), Mexico; DOB 21 Aug 1978; POB Guaymas, Sonora, Mexico; nationality Mexico; Gender Male; C.U.R.P. ROFJ780821HSRMGR10 (Mexico) (individual) [SDNTK]. Designated pursuant to section 805(b)(2) of the Foreign Narcotics Kingpin Designation Act (Kingpin Act), 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of, Sergio VALENZUELA VALENZUELA.

4. PINEDA ARMENTA, Leonardo (a.k.a. "EL 20"; a.k.a. "EL TWENTY"; a.k.a. "EL VEINTE"), Mexico; DOB 31 Mar 1970; POB Los Mochis, Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. PIAL700331HSLNRN00 (Mexico) (individual) [SDNTK]. Designated pursuant to section 805(b)(2) of the Foreign Narcotics Kingpin Designation Act (Kingpin Act), 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of, Sergio VALENZUELA VALENZUELA.

5. CARRILLO JIMENEZ, Luis Alberto, Mexico; DOB 15 Aug 1979; POB Nogales, Sonora, Mexico; nationality Mexico; Gender Male; C.U.R.P. CAJL790815HSRRMS05 (Mexico) (individual) [SDNTK]. Designated pursuant to section 805(b)(2) of the Foreign Narcotics Kingpin Designation Act (Kingpin Act), 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of, Sergio VALENZUELA VALENZUELA.

6. ROCHIN HURTADO, Meliton (a.k.a. "EL 63"; a.k.a. "EL SIXTY THREE"), Mexico; DOB 28 Oct 1975; POB Hermosillo, Sonora, Mexico; nationality Mexico; Gender Male; C.U.R.P. ROHM751028HSRCRL00 (Mexico) (individual) [SDNTK]. Designated pursuant to section 805(b)(2) of the Foreign Narcotics Kingpin Designation Act (Kingpin Act), 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of, Sergio VALENZUELA VALENZUELA.

7. MARRUFO CABRERA, Miguel Raymundo, Tlaxcala No. 10, Col. Valle Dorado 10, Cananea, Sonora 84620, Mexico; DOB 11 Sep 1963; POB Naco, Sonora, Mexico; nationality Mexico; Gender Male; C.U.R.P. MACM630911HSRRBG02 (Mexico) (individual) [SDNTK]. Designated pursuant to section 805(b)(2) of the Foreign Narcotics Kingpin Designation Act (Kingpin Act), 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of, Sergio VALENZUELA VALENZUELA.

8. VALENZUELA VALENZUELA, Sergio (a.k.a. "GIGIO"; a.k.a. "YIYO"), Mexico; DOB 20 Aug 1969; POB Los Mochis, Sinaloa, Mexico; nationality Mexico; Gender Male; C.U.R.P. VAVS690820HSLLLR00 (Mexico)

(individual) [SDNTK]. Designated pursuant to section 805(b)(2) of the Foreign Narcotics Kingpin Designation Act (Kingpin Act), 21 U.S.C. 1904(b)(2), for materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of, the SINALOA CARTEL and Ismael ZAMBADA GARCIA.

Entities

1. ACUAINDUSTRIA NARCISO MENDOZA, S.C. DE R.L. DE C.V., Hermosillo, Sonora, Mexico; Organization Established Date 17 Sep 2004; Folio Mercantil No. 33649 (Mexico) [SDNTK] (Linked To: ROCHIN HURTADO, Meliton). Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Meliton ROCHIN HURTADO [SDNTK].

2. CLUB INDIOS ROJOS DE JUAREZ, S.A. DE C.V., Ciudad Juarez, Chihuahua, Mexico; Organization Established Date 05 Apr 2005; Folio Mercantil No. 21708 (Mexico) [SDNTK] (Linked To: MARRUFO CABRERA, Miguel Raymundo). Designated pursuant to section 805(b)(3) of the Kingpin Act, 21 U.S.C. 1904(b)(3), for being owned, controlled, or directed by, or acting for or on behalf of, Miguel Raymundo MARRUFO CABRERA [SDNTK].

Dated: September 22, 2021.

Bradley T. Smith,

Acting Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2021-20899 Filed 9-24-21; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Department of the Treasury.
ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of persons whose property and interests in property have been unblocked and removed from the list of Specially Designated Nationals and Blocked Persons.

DATES: See **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel: 202-622-2420; Assistant Director for Licensing, tel.: 202-622-2480; Assistant Director for Regulatory Affairs, tel.: 202-622-4855; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202-622-2490; or the Department of the Treasury's Office of the General Counsel: Office of the Chief

Counsel (Foreign Assets Control), tel.: 202-622-2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The list of Specially Designated Nationals and Blocked Persons (SDN List) and additional information concerning OFAC sanctions programs are available on OFAC's website (<http://www.treasury.gov/ofac>).

Notice of OFAC Actions

On September 22, 2021, OFAC determined that the property and interests in property of the following persons are unblocked and removed from the SDN List.

Individuals

1. FREGOSO GONZALEZ, Marco Antonio, Av. Patria 2085, Mezzanine, Col. Puerta de Hierro, Guadalajara, Jalisco 45116, Mexico; Francisco Javier Gamboa 388-201, Col. Americana, Guadalajara, Jalisco 44110, Mexico; DOB 23 Sep 1978; POB Zapopan, Jalisco, Mexico; citizen Mexico; Gender Male; Passport G01106795 (Mexico); R.F.C. FEGM780923PH4 (Mexico); C.U.R.P. FEGM780923HJCRNR01 (Mexico); alt. C.U.R.P. FEGM780923HJCRNR19 (Mexico) (individual) [SDNTK] (Linked To: GRUPO NUTRICIONAL ALHOMA, S.A. DE C.V.).

2. HEREDIA HORNER, Mauricio, Calle Ceja de la Barranca 500-4, Fracc. Loma Real, Zapopan, Jalisco 45110, Mexico; Blvd. Puerta de Hierro 5210-6, Col. Puerta de Hierro, Zapopan, Jalisco 45116, Mexico; J.J. Martinez Aguirre 4248, Ciudad de los Ninos, Zapopan, Jalisco 45040, Mexico; Toluca 3134, Fracc. Monraz, Guadalajara, Jalisco 44670, Mexico; Eulogio Parra 3200, Piso 2, Local 21, Fracc. Monraz, Guadalajara, Jalisco 44670, Mexico; Popocatepetl 2907-1, Col. Ciudad del Sol, Zapopan, Jalisco, Mexico; DOB 29 Jul 1978; POB Guadalajara, Jalisco, Mexico; citizen Mexico; Gender Male; R.F.C. HEHM780729FZ5 (Mexico); alt. R.F.C. HEHM780729HJC (Mexico); C.U.R.P. HEHM780729HJCRRR07 (Mexico) (individual) [SDNTK] (Linked To: ESCUELA DE FUTBOL RAFAEL MARQUEZ, ASOCIACION CIVIL; Linked To: FUTBOL Y CORAZON, ASOCIACION CIVIL; Linked To: GRUPO DEPORTIVO ALVANER, S.A. DE C.V.; Linked To: GRUPO DEPORTIVO MARQUEZ PARDO, S. DE R.L. DE C.V.; Linked To: GRUPO NUTRICIONAL ALHOMA, S.A. DE C.V.; Linked To: GRUPO TERAPEUTICO HORMARAL, S.A. DE C.V.; Linked To: GRUPO TERAPEUTICO PUERTO VALLARTA, S.A. DE C.V.; Linked To: PROSPORT & HEALTH IMAGEN, S.A. DE C.V.; Linked To: SERVICIOS EDUCATIVOS Y DE NEGOCIOS, S. DE R.L. DE C.V.).

3. MARQUEZ ALVAREZ, Rafael (a.k.a. MARQUEZ, Rafa), Calle Popocatepetl 2907-1, Col. Ciudad del Sol, Zapopan, Jalisco, Mexico; Toluca 3134, Fracc. Monraz, Guadalajara, Jalisco 44670, Mexico; Av. Patria 2085, Mezzanine, Col. Puerta de Hierro, Zapopan, Jalisco 45116, Mexico; Moliere 330-303, Col. Polanco, Mexico, Distrito Federal 11560, Mexico; J.J. Martinez

Aguirre 4248, Ciudad de los Ninos, Zapopan, Jalisco 45040, Mexico; Blvd. Adolfo Lopez Mateos 1810, Col. La Martinica, Leon, Guanajuato, Mexico; DOB 13 Feb 1979; POB Zamora, Michoacan de Ocampo, Mexico; citizen Mexico; Gender Male; R.F.C. MAAR7902132V4 (Mexico); C.U.R.P. MAAR790213HMRNLF03 (Mexico) (individual) [SDNTK] (Linked To: ESCUELA DE FUTBOL RAFAEL MARQUEZ, ASOCIACION CIVIL; Linked To: FUTBOL Y CORAZON, ASOCIACION CIVIL; Linked To: GRUPO DEPORTIVO ALVANER, S.A. DE C.V.; Linked To: FLORES DRUG TRAFFICKING ORGANIZATION; Linked To: GRUPO DEPORTIVO MARQUEZ PARDO, S. DE R.L. DE C.V.; Linked To: GRUPO NUTRICIONAL ALHOMA, S.A. DE C.V.; Linked To: GRUPO TERAPEUTICO HORMARAL, S.A. DE C.V.; Linked To: GRUPO TERAPEUTICO PUERTO VALLARTA, S.A. DE C.V.; Linked To: PROSPORT & HEALTH IMAGEN, S.A. DE C.V.).

4. ABOUZAID EL BAYEH, Salime, Paseo de los Virreyes 951-A20, Fraccionamiento Virreyes, Zapopan, Jalisco, Mexico; DOB 28 Nov 1983; POB Guadalajara, Jalisco, Mexico; Gender Female; C.U.R.P. AOB5831128MJCBL09 (Mexico) (individual) [SDNTK] (Linked To: COMERCIALIZADORA TRADE CLEAR, S.A. DE C.V.; Linked To: GRUPO DE ALTA ESPECIALIDAD FARMACEUTICA, S.A. DE C.V.; Linked To: LOS CUINIS; Linked To: CARTEL DE JALISCO NUEVA GENERACION).

5. MONJE ALVARADO, Jonh Eduarth; DOB 09 May 1969; POB Caqueta, Florencia, Colombia; Cedula No. 1673727 (Colombia) (individual) [SDNTK] (Linked To: AGRO NEGOCIOS SAJE LTDA.).

6. CHEAITELLY SAHELI, Ali Hassan (a.k.a. CHEAITELLI, Hassan; a.k.a. "CHEAITELLY, Alex"); DOB 05 Sep 1983; POB Colon, Panama; Cedula No. 3-712-2418 (Panama) (individual) [SDNTK] (Linked To: PRODUCERS GROUP CORP.; Linked To: SANTA MARIA INTERNATIONAL TRADING CORP.; Linked To: SILVER HOUSE, INC.; Linked To: EUROCAMBIO, S.A.; Linked To: INMOBILIARIA DAVITOV S.A.; Linked To: FUNDACION H.M.M.).

7. FADLALLAH CHEAITELLY, Jorge (a.k.a. CHEAITELLY SAHELE, Jorge Ali; a.k.a. "GIORGIO"); DOB 20 Dec 1960; POB Maicao, La Guajira, Colombia; Cedula No. 17849451 (Colombia) (individual) [SDNTK] (Linked To: RESTAURANTE BEIRUT MEXICO S.A. DE C.V.; Linked To: BODEGA ELECTRO GIORGIO; Linked To: EUROCAMBIO, S.A.; Linked To: GENERAL COMMERCE OVERSEAS, INC.; Linked To: PRODUCERS GROUP CORP.; Linked To: ZEDRO INVESTMENT, S.A.; Linked To: GIORGINO CORPORATION OF PANAMA, S.A.; Linked To: GIORGIO CHEAITELLY INVESTMENT, S.A.; Linked To: GIORGIOTELLY, S.A.; Linked To: III MILLENIUM INTERNATIONAL, S.A.; Linked To: J.H. EXIM INTERNACIONAL, S.A.; Linked To: SANTA MARIA INTERNATIONAL TRADING CORP.; Linked To: SILVER HOUSE, INC.; Linked To: OCEAN INDIC OVERSEAS, S.A.; Linked To: JUNIOR INTERNATIONAL S.A.; Linked To: CAFE DU LIBAN, S.A.).

8. FADLALLAH CHEAYTELLI, Jaime, c/o GENERAL COMMERCE OVERSEAS, INC.; c/o EURO EXCHANGE Y FINANCIARIAL COMMERCE, INC.; DOB 18 Jul 1967; POB Maicao, La Guajira, Colombia; Cedula No. 84048039 (Colombia) (individual) [SDNTK].

9. FADLALLATH CHEAITILLY, Fatima (a.k.a. FADLALLAH CHEAITELLY, Fatima), c/o ZEDRO INVESTMENT, S.A.; c/o GIORGINO CORPORATION OF PANAMA, S.A.; c/o GIORGIO CHEAITELLY INVESTMENT, S.A.; c/o SILVER HOUSE, INC.; c/o ALMACEN ELECTRO SONY STAR; c/o COMERCIAL GLOBANTY; DOB 08 Dec 1972; POB Maicao, La Guajira, Colombia; Cedula No. 56083194 (Colombia) (individual) [SDNTK].

10. MARTINEZ LASSO, Vielka Judith; DOB 09 Nov 1967; POB El Higo, San Carlos, Panama; Cedula No. 8-283-646 (Panama) (individual) [SDNTK] (Linked To: INVERSIONES OMEGA INTERNACIONAL S.A.; Linked To: EURO FINANCING, CORP.; Linked To: EUROCAMBIO INVESTMENT S.A.; Linked To: INVERSIONES TROL PANAMA S.A.; Linked To: EUROCAMBIO, S.A.; Linked To: BEAUTY STATION, S.A.).

11. MORAN SANCHEZ, Maria Janette (a.k.a. MORAN SANCHEZ, Janet); DOB 15 Nov 1956; POB Panama; Cedula No. 2-84-1948 (Panama) (individual) [SDNTK] (Linked To: BERLIN INDUSTRIES, CORP.; Linked To: INVERSIONES OMEGA INTERNACIONAL S.A.; Linked To: EURO FINANCING, CORP.; Linked To: EUROCAMBIO INVESTMENT S.A.; Linked To: BEAUTY STATION, S.A.; Linked To: INVERSIONES TROL PANAMA S.A.).

12. PLATA RIVERA, Ignacio Eduardo; DOB 01 Jan 1935; POB Panama City, Panama; citizen Panama; Cedula No. 8-78-897 (Panama) (individual) [SDNTK] (Linked To: GENERAL COMMERCE OVERSEAS, INC.; Linked To: EURO FINANCING, CORP.; Linked To: EUROCAMBIO, S.A.).

13. OMEARA NAVARRO, Marylu (a.k.a. OMEARA NAVARRO DE CHEAITELLY, Marylu; a.k.a. OMEARA NAVARRO, Mary Lu); DOB 12 Feb 1960; POB Colombia; Cedula No. E-8-101804; Passport AB304459 (Colombia) (individual) [SDNTK] (Linked To: INMOBILIARIA DAVITOV S.A.; Linked To: FUNDACION H.M.M.; Linked To: INVERSIONES OMEGA INTERNACIONAL S.A.).

14. GRAJALES MARIN, Aura Cecilia, Carrera 15 No. 33A-53, Cali, Colombia; c/o INVERSIONES SANTA CECILIA S.C.S., La Union, Valle, Colombia; c/o INVERSIONES SANTA MONICA LTDA., La Union, Valle, Colombia; Cedula No. 21236002 (Colombia) (individual) [SDNT].

15. GRAJALES MARIN, Carlos Arturo, c/o INVERSIONES SANTA CECILIA S.C.S., La Union, Valle, Colombia; c/o INVERSIONES SANTA MONICA LTDA., La Union, Valle, Colombia; Cedula No. 63568339 (Colombia) (individual) [SDNT].

16. GRAJALES POSSO, Gloria Amparo, c/o IBADAN LTDA., Tulua, Valle, Colombia; c/o INVERSIONES AGUILA LTDA., La Union, Valle, Colombia; Cedula No. 29613755 (Colombia) (individual) [SDNT].

Entities

1. ESCUELA DE FUTBOL RAFAEL MARQUEZ, ASOCIACION CIVIL (a.k.a. ESC

DE FUTBOL RAFAEL MARQUEZ; a.k.a. ESCUELA DE FUTBOL RAFAEL MARQUEZ), Guadalajara, Jalisco, Mexico; Av. del Bajio 1134, Col. El Bajio, Guadalajara, Jalisco, Mexico; Del Bajio 1134, San Juan de Ocotan, Guadalajara, Jalisco, Mexico; Folio Mercantil No. 23461 (Jalisco) (Mexico) [SDNTK].

2. FUTBOL Y CORAZON, ASOCIACION CIVIL (a.k.a. CENTRO INFANTIL RM; a.k.a. FUNDACION FUTBOL Y CORAZON, A.C.; a.k.a. FUNDACION RAFA MARQUEZ; a.k.a. FUNDACION RAFA MARQUEZ FUTBOL Y CORAZON, A.C.; a.k.a. FUTBOL Y CORAZON, A.C.; a.k.a. RAFA MARQUEZ FOUNDATION), Guadalajara, Jalisco, Mexico; Av. Xochitl 4262-6, Prados del Tepeyac, Zapopan, Jalisco 45050, Mexico; Popocatepetl 2907, Col. Ciudad del Sol, Zapopan, Jalisco 45050, Mexico; Santa Isabel 62, Col. Santa Isabel, Tonalá, Jalisco, Mexico; Lic. Alfonso Garcia Robles 74, Col. Adolfo Lopez Mateos, Zamora, Michoacan, Mexico; Privada Primitivo Torres 52, Col. El Terrero, El Quince, El Salto, Jalisco 45680, Mexico; alt. Website www.fundacionrafamarquez.org; R.F.C. FCO0505306V0 (Mexico); Folio Mercantil No. 10328 (Jalisco) (Mexico) [SDNTK].

3. GRUPO DEPORTIVO ALVANER, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Folio Mercantil No. 72016 (Jalisco) (Mexico) [SDNTK].

4. GRUPO DEPORTIVO MARQUEZ PARDO, S. DE R.L. DE C.V., Guadalajara, Jalisco, Mexico; Popocatepetl 2907-1, Col. Ciudad del Sol, Zapopan, Jalisco 45050, Mexico; R.F.C. GDM090907NE0 (Mexico); Folio Mercantil No. 51360 (Jalisco) (Mexico) [SDNTK].

5. GRUPO NUTRICIONAL ALHOMA, S.A. DE C.V., Guadalajara, Jalisco, Mexico; Av. Lopez Mateos Sur 1710-4, Fracc. El Palomar, Tlajomulco de Zuniga, Jalisco 45643, Mexico; R.F.C. GNA120828LL8 (Mexico); Folio Mercantil No. 69366 (Jalisco) (Mexico) [SDNTK].

6. GRUPO TERAPEUTICO HORMARAL, S.A. DE C.V. (a.k.a. GRUPO TERAPEUTICO HERMORAL, S.A. DE C.V.; a.k.a. PROSPORT & HEALTH; a.k.a. PROSPORT & HEALTH), Guadalajara, Jalisco, Mexico; Av. General Eulogio Parra 3200-21, Fracc. Terrazas Monraz, Guadalajara, Jalisco 44670, Mexico; Calle Lisboa 175, Col. Versalles, Puerto Vallarta, Jalisco, Mexico; website www.prosport.mx; R.F.C. GTH1206069J8 (Mexico); Folio Mercantil No. 68188 (Jalisco) (Mexico) [SDNTK].

7. GRUPO TERAPEUTICO PUERTO VALLARTA, S.A. DE C.V. (a.k.a. GRUPO TERAPEUTICO DE VALLARTA, S.A. DE C.V.; a.k.a. PROSPORT & HEALTH), Puerto Vallarta, Jalisco, Mexico; Lisboa 175, Col. Versalles, Puerto Vallarta, Jalisco 48320, Mexico; Folio Mercantil No. 16405 (Jalisco) (Mexico) [SDNTK].

8. PROSPORT & HEALTH IMAGEN, S.A. DE C.V. (a.k.a. PROSPORT & HEALTH, S.A. DE C.V.; a.k.a. PROSPORT Y HEALTH IMAGEN, S.A. DE C.V.), Guadalajara, Jalisco, Mexico; Calle Golfo de Cortes 4114, Local 4 y 5, Col. Monraz, Guadalajara, Jalisco 44670, Mexico; website www.pshimagen.mx; R.F.C. PAH130925LG0 (Mexico); alt. R.F.C.

PAH130925IG0 (Mexico); Folio Mercantil No. 77129 (Jalisco) (Mexico) [SDNTK].

9. SERVICIOS EDUCATIVOS Y DE NEGOCIOS, S. DE R.L. DE C.V., Zapopan, Jalisco, Mexico; Folio Mercantil No. 51560 (Jalisco) (Mexico) [SDNTK].

10. GRUPO DE ALTA ESPECIALIDAD FARMACEUTICA, S.A. DE C.V., Av. Vallarta No. 3133, Col. Vallarta Poniente, Guadalajara, Jalisco 44110, Mexico; Toltecas 3579, Colonia Santa Rita, Zapopan, Jalisco, Mexico; R.F.C. GAE-060123-3TA (Mexico) [SDNTK].

11. AGRO NEGOCIOS SAJE LTDA., Carrera 15A No. 121-12, Ofc. 504, Bogota, Colombia; NIT # 9002933274 (Colombia); Matricula Mercantil No 1903808 (Colombia) [SDNTK].

12. BODEGA ELECTRO GIORGIO, Calle 14 No. 8-67, Maicao, La Guajira, Colombia; Matricula Mercantil No 00027344 (Colombia) [SDNTK].

13. CAFE DU LIBAN, S.A., Avenida Eloy Alfaro, Panama City, Panama; RUC # 36266-1-368869 (Panama) [SDNTK].

14. COMERCIAL GLOBANTY, Calle 13, No. 10-19, Local 02, Maicao, La Guajira, Colombia; Calle 13, No. 10-36, Maicao, La Guajira, Colombia; NIT # 56083194-1 (Colombia); Matricula Mercantil No 102964 (Colombia) [SDNTK].

15. EURO EXCHANGE Y FINANCIAL COMMERCE, INC. (a.k.a. "EUREX"), Avenida Eusebio A Morales y Via Veneto—Hotel Veneto, Planta Baja, Local 6, Panama City, Panama; Edificio Servicios Aeroportuarios, Segundo Piso, Local 12, Panama City, Panama; RUC # 1652278-1-675861 (Panama) [SDNTK].

16. EUROCAMBIO, S.A. (a.k.a. "CASA DE CAMBIO EUROCAMBIO"), Calle Ricardo Arias, Edificio Macondo, Local 2-A, Panama City, Panama; RUC # 17762-1-366473 (Panama) [SDNTK].

17. FUNDACION H.M.M., Panama City, Panama; RUC # 1767437-1-41487 (Panama) [SDNTK].

18. GENERAL COMMERCE OVERSEAS, INC., Calle Ricardo Arias, Edificio Macondo, Local 2-A, Panama City, Panama; RUC # 1109850-1-561818 (Panama) [SDNTK].

19. GIORGINO CORPORATION OF PANAMA, S.A., Panama; RUC # 27216-2-227535 (Panama) [SDNTK].

20. GIORGIO CHEAITELLY INVESTMENT, S.A., Panama; RUC # 31850-2-245132 (Panama) [SDNTK].

21. GIORGIOTELLY, S.A., Panama; RUC # 33518-38-252229 (Panama) [SDNTK].

22. III MILLENIUM INTERNATIONAL, Panama; RUC # 16927-1-366365 (Panama) [SDNTK].

23. INMOBILIARIA DAVITOV S.A., Panama City, Panama; RUC # 33672-51-252853 (Panama) [SDNTK].

24. INVERSIONES OMEGA INTERNACIONAL S.A., Panama; RUC # 1367799-1-621064 (Panama) [SDNTK].

25. J.H. EXIM INTERNACIONAL, S.A., Panama; RUC # 46110-70-302460 (Panama) [SDNTK].

26. OCEAN INDIC OVERSEAS, S.A., Panama; RUC # 21523-11-193299 (Panama) [SDNTK].

27. PRODUCERS GROUP CORP., Panama; RUC # 59443-40-344348 (Panama) [SDNTK].

28. RESTAURANTE BEIRUT MEXICO S.A. DE C.V. (a.k.a. RESTAURANTE BAR BEIRUT

Y LAS MIL Y UNA NOCHES), Juan Salvador Agraz No. 50, Colonias Lomas de Santa Fe, Delegacion Cuajimalpa, Ciudad de Mexico, Mexico; RFC RBM-1000208-KB5 (Mexico) [SDNTK].

29. SANTA MARIA INTERNATIONAL TRADING CORP., Panama; RUC # 45579-11-300568 (Panama) [SDNTK].

30. SILVER HOUSE, INC., Panama; RUC # 1258011-1-80105701 (Panama) [SDNTK].

31. ZEDRO INVESTMENT, S.A., Panama; RUC # 31906-42-245391 (Panama) [SDNTK].

32. BEAUTY STATION, S.A., Panama City, Panama; RUC # 2224264-1-776957 (Panama) [SDNTK].

33. BERLIN INDUSTRIES, CORP., Panama City, Panama; RUC # 748891-1-479617 (Panama) [SDNTK].

34. BERLIN INTERNACIONAL S.A., Colon, Panama; RUC # 4392-35-59025 (Panama) [SDNTK].

35. EURO FINANCING, CORP., Panama; RUC # 1579574-1-662275 (Panama) [SDNTK].

36. EUROCAMBIO INVESTMENT S.A., Panama; RUC # 1561469-1-659119 (Panama) [SDNTK].

37. INVERSIONES TROL PANAMA S.A., Panama; RUC # 1950017-1-731674 (Panama) [SDNTK].

Dated: September 22, 2021.

Gregory T. Gatjanis,

Associate Director, Office of Global Targeting, Office of Foreign Assets Control.

[FR Doc. 2021-20909 Filed 9-24-21; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF THE TREASURY

Senior Executive Service Performance Review Boards

AGENCY: Department of the Treasury.

ACTION: Notice of appointments to Performance Review Boards (PRBs).

SUMMARY: Pursuant to 5 U.S.C. 4314(c)(4), this notice announces the appointment of members to the Department of the Treasury's Performance Review Boards (PRBs). The purpose of these Boards are to review and make recommendations concerning proposed performance appraisals, ratings, bonuses and other appropriate personnel actions for incumbents of SES positions in the Department.

Composition of the PRB: The Boards shall consist of at least three members. In the case of an appraisal of a career appointee, more than half the members shall consist of career appointees. The persons listed below may be selected to serve on one or more PRB within Treasury.

Names for Federal Register Publication

Top Officials

- Leonard Olijar, Director for the Bureau of Engraving and Printing

- Patricia Greiner, Deputy Director for Bureau of Engraving and Printing and Chief Administrative Officer
- Charlene William, Deputy Director for Bureau of Engraving and Printing and Chief Operating Officer
- Timothy Gribben, Commissioner for the Bureau of the Fiscal Service
- Tami Perriello, Deputy Commissioner (Finance and Administration), Bureau of the Fiscal Service
- Matthew J. Miller, Deputy Commissioner (Accounting and Shared Services), Bureau of the Fiscal Service
- Jeffrey J. Schramek, Deputy Commissioner (Financial Services and Operations), Bureau of the Fiscal Service
- Jeffrey Tribiano, Deputy Commissioner for Operations Support (IRS)
- Douglas O'Donnell, Deputy Commissioner for Services and Enforcement (IRS)
- Mary G. Ryan, Administrator for the Alcohol and Tobacco Tax and Trade Bureau
- AnnaLou Tirol, Deputy Director, Financial Crimes Enforcement Network
- David Lebyrk, Fiscal Assistant Secretary
- Laurie Schaffer, Principal Deputy General Counsel
- Addar, Levi, Deputy General Counsel

Departmental Offices

- John M. Farley, Director, Executive Office for Asset Forfeiture
- Benjamin Harris, Counselor to the Secretary
- Marti Penthy Adams-Baker, Executive Secretary
- Donna Ragucci, Director for the Office of Small and Disadvantaged Business Utilization
- Elizabeth S. Rosenberg, Counselor to the Deputy Secretary
- Alfred Johnson, Deputy Chief of Staff
- Julie Siegel, Deputy Chief of Staff
- Jonathan Davidson, Counselor
- John Morton, Climate Counselor
- David Lipton, Counselor
- Brian Reissaus, Director, Investment Security
- Joseph Phillip Ludvigson, Director, Monitoring and Enforcement
- Patricia Pollard, Deputy Assistant Secretary for International Money and Financial Policy
- Matthew J. Mohlenkamp, Director, South and South East Asia
- Brian McCauley, Director, Office of Europe and Eurasia
- Clarence Severens, Director, Office of Development Results and Accountability
- Andy Baukol, Principal Deputy Assistant Secretary for International Monetary Policy

- Matthew Haarsager, Deputy Assistant Secretary for International Development Finance and Policy
- Robert Kaproth, Deputy Assistant Secretary for South and East Asia
- Michael Kaplan, Deputy Assistant Secretary for Western Hemisphere and South Asia
- Albert Lee, Director, Market Rooms
- William McDonald, Deputy Assistant Secretary for Technical Assistance Policy
- Lailee Moghtader, Deputy Assistant Secretary for Trade Policy
- Charles Moravec, Director, Multilateral Development Banks
- Jeffrey K. Baker, Deputy Assistant Secretary for Investment, Energy and Infrastructure
- Lida Fitts, Director, Energy and Infrastructure
- Anthony Ieronimo, Director, Office of Trade Finance
- Eric Meyer, Deputy Assistant Secretary for Africa, Middle East and MDB Operations
- Jason R. Orlando, Director, Office of Technical Assistance
- Matthew Swineheart, Director, International Financial Markets
- Stephen Ledbetter, Director of Policy
- Amy Edwards, Deputy Assistant Secretary (Accounting Policy and Financial Transparency)
- Gregory Till, Deputy Assistant Secretary for Fiscal Operations and Policy
- Christopher H. Kubeluis, Director for the Office of Fiscal Projections
- Theodore R. Kowalsky, Director for the Office of Grants and Asset Management
- Walter Kim, Director for the Office of Financial Institutions and Policy
- Felton Booker, Deputy Assistant Secretary, Financial Institution Policy
- Noel Poyo, Deputy Assistant Secretary for Community and Economic Development
- Christopher Weaver, Director, Office of Community and Economic Development
- Brian Peretti, Director of International Coordination and Mission Support
- Steven E. Seitz, Director for the Office of Federal Insurance Office
- Stephanie Schmelz, Deputy Director, Federal Insurance
- Rahul Prabhakar, Deputy Assistant Secretary for Cybersecurity and Critical Infrastructure
- Paul Neff, Director of Cyber Policy, Preparedness and Response
- Jodie L. Harris, Director for Community Development and Financial Institutions
- Dennis E. Nolan, Deputy Director for Finance and Operations
- Marcia Sigal, Deputy Director for Policy and Programs
- Brian M. Smith, Deputy Assistant Secretary for Federal Finance
- Gary Grippio, Deputy Assistant Secretary for Government Financial Policy
- Bonnie Adair Morse, Deputy Assistant Secretary for Capital Access
- Jeffrey Stout, Director of Federal Program Finance
- Fred Pietrangeli, Director for the Office of Debt Management
- Daniel J. Harty, Director, Capital Markets
- Melissa Moye, Director for State and Local Finance
- Andrea Gacki, Director for the Office of Foreign Assets Control
- Bradley T. Smith, Deputy Director for the Office of Foreign Assets Control
- Gregory Gatjanis, Associate Director for the Office of Global Targeting
- Lisa M. Palluconi, Associate Director for the Office of Program Policy and Implementation, Office of Foreign Assets Control
- John H. Battle, Associate Director for Resource Management, Office of Foreign Assets Control
- Billy Bradley, Deputy Director, Treasury Executive Office for Asset Forfeiture
- Lawrence Scheinert, Associate Director for the Office of Compliance and Enforcement
- Ripley Quinby, Deputy Associate Director, Office of Global Targeting
- Paul Ahern, Principal Deputy Assistant Secretary for Terrorist Financing and Financial Crimes
- Scott Rembrandt, Deputy Assistant Secretary for the Office of Strategic Policy, Terrorist Financing and Financial Crimes
- Anna Morris, Deputy Assistant Secretary for Global Affairs
- Rhett Skiles, Deputy Assistant Secretary, Cyber Intelligence
- Katherine Amlin, Deputy Assistant Secretary for Analysis and Production
- Thomas J. Wolverton, Deputy Assistant Secretary for Security and Counterintelligence
- Michael Neufeld, Principal Deputy Assistant Secretary for Support and Technology
- Patrick Conlon, Director for the Office of Economics and Finance
- Everette E. Jordan, Deputy Assistant Secretary for Intelligence Community Integration
- Todd Conklin, Chief Information Officer, Intelligence Platform and Innovation
- Aruna Kalyanam, Deputy Assistant Secretary for Legislative Affairs (Tax and Budget)
- Angel Nigaglioni, Deputy Assistant Secretary for Legislative Affairs (Appropriations and Management)
- Craig Radcliffe, Deputy Assistant Secretary for Legislative Affairs (Banking)
- Lily A. Adams, Principal Deputy Assistant Secretary for Public Affairs
- Antonio White, Deputy Assistant Secretary for Community Engagement
- Natasha R. Sarin, Deputy Assistant Secretary for Microeconomic Analysis
- Christopher J. Soares, Director, Office of Microeconomic Analysis
- Catherine Wolfram, Deputy Assistant Secretary, Climate and Energy Economics
- Jonathan S. Jaquette, Director for Receipts Forecasting
- Mark Mazur, Deputy Assistant Secretary for Tax Policy
- Neviana Petkova, Director for Individual Business and International Taxation
- Edith Brashares, Director for the Office of Tax Analysis
- Curtis Carlson, Director for Business Revenue
- Adam Cole, Director for Individual Taxation
- Timothy E. Skud, Deputy Assistant Secretary for Tax, Trade and Tariff Policy
- Robert E. Gillette, Director for Economic Modeling and Computer Applications
- Kimberly Clausen, Deputy Assistant Secretary for Tax Analysis
- Jose Murillo, Deputy Assistant Secretary for International Tax Affairs
- Thomas West, Deputy Assistant Secretary for Domestic Business Tax
- Itai Grinberg, Deputy Assistant Secretary for Multilateral Tax
- Rebecca Kysar, Counselor
- Ryan Law, Deputy Assistant Secretary for Privacy Transparency and Records
- Robert Mahaffie, Deputy Assistant Secretary for Management and Budget
- Tonya Burton, Director for the Office of Financial Management
- Lenora Stiles, Director, Strategic Planning and Performance Improvement
- Stephen Cotter, Director, Special Entity Accounting
- William Sessions, Departmental Budget Director
- Carole Y. Banks, Deputy Chief Financial Officer
- Nicole K. Evans, Director, Office of Procurement Executive
- J. Trevor Norris, Deputy Assistant Secretary for Human Resources and Chief Human Capital Officer
- Lorraine Cole, Director, Office of Minority and Women Inclusion
- Colleen Heller-Stein, Human Resource Officer for Departmental Offices/Deputy Chief Human Capital Officer
- Nancy Ostrowski, Director of DC Pensions

- David Aten, Director, Integrated Talent Management Implementation
- Antony P. Arcadi, Associate Chief Information Officer for Enterprise Infrastructure Operations
- Nicolaos Totten, Associate Chief Information Officer for Enterprise Application Services
- Michael O. Thomas, Deputy Assistant Secretary for Treasury Operations

Office of the General Counsel

- Hanoi Veras, Deputy Assistant General Counsel (Ethics)
- Heather Trew, Assistant General Counsel (Enforcement and Intelligence)
- Frank P. Menna, Deputy Assistant General Counsel (Enforcement and Intelligence)
- Jacob Loshin, Deputy Assistant General Counsel (Enforcement and Intelligence)
- Jason M. Prince, Chief Counsel, Office of Foreign Assets Control
- Eric Froman, Assistant General Counsel (Banking and Finance)
- Stephen Milligan, Deputy Assistant General Counsel (Banking and Finance)
- Theodore Posner, Assistant General Counsel (International Affairs)
- Alexandra Yestrumskas, Deputy Assistant General Counsel (International Affairs)
- Jeffrey M. Klein, Deputy Assistant General Counsel (International Affairs)
- Brian J. Sonfield, Assistant General Counsel (General Law, Ethics and Regulation)
- Michael Briskin, Deputy Assistant General Counsel (General Law and Regulation)
- Kevin Nichols, International Tax Counsel
- Krishna Prasad Vallabhaneni, Tax Legislative Counsel
- Carol Ann Weiser, Benefits Tax Counsel
- Helen Morrison, Deputy Benefits Tax Counsel
- Brett Steven York, Deputy Tax Legislative Counsel
- Michelle Dickerman, Deputy Assistant General Counsel for Oversight and Litigation
- Katrina Carroll, Chief Counsel for the Financial Crimes Enforcement Network
- Heather Book, Chief Counsel for the Bureau of Engraving and Printing
- John F. Schorn, Chief Counsel for the U.S. Mint
- Lillian Lai-Lin Cheng, Chief Counsel for the Bureau of the Fiscal Service
- Anthony P. Gledhill, Chief Counsel for the Tax and Trade Bureau

Bureau of Engraving and Printing

- Judith Diazmyers, Senior Advisor
- Steven Fisher, Associate Director (Chief Financial Officer)
- Richard Roy Clark, Associate Director (Quality)
- Frank Freeman III, Associate Director (Management)
- Justin D. Draheim, Associate Director (Product Design and Development)
- Harinder Singh, Associate Director, (Chief Information Officer)
- Yolanda Ward, Associate Director, Manufacturing (DCF)

Financial Crimes Enforcement Network

- Himamauli Das, Counselor to the Director of the Financial Crimes and Enforcement Network
- Amy L. Taylor, Associate Director, Technology Solutions and Services/CIO
- Peter Bergstrom, Associate Director, Management/CFO
- Felicia Swindells, Associate Director, Policy Division
- Jimmy Kirby Jr, Associate Director, Intelligence Division
- Kenneth L. O'Brien, Deputy Associate Director, Chief Technology Officer
- Matthew R. Stiglitz, Associate Director, Global Investigations Division
- Timothy Ott, Strategic Advisor

U.S. Mint

- Matthew Holben, Associate Director for Sales and Marketing/Chief Marketing and Sales Officer
- Kristie L. McNally, Associate Director for Financial Management/CFO
- David Croft, Associate Director for Manufacturing
- Francis O'Hearn, Associate Director for Information Technology
- Robert Kuryzna, Plant Manager, Philadelphia
- B.B. Craig, Associate Director for Environment, Safety and Health
- Allison Doone, Chief Administrative Officer
- Randall Johnson, Plant Manager for Denver

Tax and Trade Bureau

- Daniel T. Riordan, Assistant Administrator, Permitting and Taxation
- Cheri Mitchell, Assistant Administrator, Management/CFO
- Robert Hughes, Assistant Administrator, Information Resources/CIO
- Elisabeth C. Kann, Assistant Administrator, External Affairs/Chief of Staff

Bureau of the Fiscal Service

- Keith Alderson, Director (DMSOC-East)

- Douglas Anderson, Assistant Commissioner (Retail Securities Services)
- Daniel Berger, Deputy Assistant Commissioner (Management)
- Linda C. Chero, Director, (RFC Philadelphia)
- David T. Copenhaver, Assistant Commissioner (Wholesale Securities Services)
- Christina M. Cox, Deputy Assistant Commissioner (Payment Management)
- Paul Deuley, Senior Advisor
- Peter T. Genova, Deputy Assistant Commissioner for Security Services/Deputy Chief Information Officer
- Joseph Gioeli, Assistant Commissioner (Information and Security Services)
- Adam H. Goldberg, Executive Architect (Financial Innovation)
- Jason T. Hill, Deputy Assistant Commissioner (Shared Services)
- John B. Hill, Director (Financial Innovation and Transformation)
- Wallace H. Ingram, Director (DMSOC-West)
- Amanda M. Kupfner, Deputy Assistant Commissioner for Infrastructure and Operations
- Madiha D. Latif, Director (Compliance and Reporting Group)
- D. Michael Linder, Assistant Commissioner (Fiscal Accounting)
- Tricia J. Long, Deputy Assistant Commissioner (Debt Management Services)
- Justin Marsico, Chief Data Officer (Deputy Assistant Commissioner)
- Nathaniel Reboja, Deputy Assistant Commissioner for Information Services
- Sandra Paylor, Director (Revenue Collection Group)
- Alyssa W. Riedl, Executive Director, Transforming Tax Collections
- Vona Susan Robinson, Executive Director (Kansas City)
- Tamela Saiko, Deputy Assistant Commissioner (Fiscal Accounting Operations)
- Lori Santamorenna, Executive Director (Government Securities Regulations Staff)
- Dara N. Seaman, Senior Advisor (Services and Programs)
- Thomas T. Vannoy, Deputy Assistant Commissioner (Wholesale Securities Services)
- Daniel J. Vavasour, Assistant Commissioner (Debt Management Services)

DATES: *Effective Date:* Membership is effective on the date of this notice.

FOR FURTHER INFORMATION CONTACT: Julia J. Markham or Kimberly Jackson, Office of Executive Resources, 1500

Pennsylvania Avenue NW, ATTN: 1722 Eye Street, 9th Floor, Washington, DC 20220, Telephone: 202-622-0774.

Kimberly Jackson,

Human Resources Specialist, Office of Executive Resources.

[FR Doc. 2021-20812 Filed 9-24-21; 8:45 am]

BILLING CODE 4810-25-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0734]

Agency Information Collection Activity Under OMB Review: Report of General Information, Report of First Notice of Death, Report of Nursing Home or Assisted Living Information, Report of Defense Finance and Accounting Service (DFAS), Report of Non-Receipt of Payment, Report of Incarceration, Report of Month of Death

AGENCY: Veterans Benefits Administration (VBA), Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits 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: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Refer to “OMB Control No. 2900-0734.”

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266-4688 or email maribel.aponte@va.gov. Please refer to “OMB Control No. 2900-0734” in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 CFR 3.217.

Title: VA Form 27-0820, Report of General Information, VA Form 27-0820a, Report of Death of First Notice of Death, VA Form 27-0820b, Report of Nursing Home and Assisted Living Information, VA Form 27-0820c, Report of Defense Finance and Accounting Service (DFAS), VA Form 27-0820d, Report of Non-Receipt of Payment, VA Form 27-0820e, Report of Incarceration, VA Form 27-0820f, Report of Month of Death.

OMB Control Number: 2900-0734.

Type of Review: Reinstatement with change of a previously approved collection.

Abstract: The forms will be used by VA personnel to document verbal information obtained telephonically from claimants or their beneficiary. The data collected will be used as part of the evidence needed to determine the claimant's or beneficiary's eligibility for benefits.

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 insert citation date: 86 FR 36320 September 7, 2021, pages 90922 and 90923.

Affected Public: Individuals.

Estimated Annual Burden: 212,500 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 2,550,000.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021-20919 Filed 9-24-21; 8:45 am]

BILLING CODE 8320-01-P



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Part II

Department of the Treasury

31 CFR Part 33

Department of Health and Human Services

45 CFR Parts 147, 155, and 156

Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond; Final Rule

DEPARTMENT OF THE TREASURY**31 CFR Part 33**

RIN 1505–AC78

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Parts 147, 155, and 156**

[CMS–9906–F]

RIN 0938–AU60

Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS; Monetary Offices, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This final rule sets forth revised 2022 user fee rates for issuers offering qualified health plans (QHPs) through federally-facilitated Exchanges and State-based Exchanges on the Federal platform; repeals separate billing requirements related to the collection of separate payments for the portion of QHP premiums attributable to coverage for certain abortion services; expands the annual open enrollment period and Navigator duties; implements a new monthly special enrollment period for qualified individuals or enrollees, or the dependents of a qualified individual or enrollee, who are eligible for advance payments of the premium tax credit (APTC) and whose household income does not exceed 150 percent of the Federal poverty level, available during periods of time during which APTC benefits are available such that certain applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022 under the section 9661 of the American Rescue Plan Act of 2021; repeals the recent establishment of a Direct Enrollment option for Exchanges; and modifies regulations and policies related to section 1332 waivers.

DATES: This final rule is effective on November 26, 2021.

FOR FURTHER INFORMATION CONTACT: Adrienne Patterson, (410) 786–0686, Jacquelyn Rudich, (301) 492–5211, or Nora Simmons, (410) 786–1981, for general information.

Gian Johnson, (301) 492–4323, or Meredith Woody, (301) 492–4404, for matters related to Navigator program standards.

Robert Yates, (301) 492–5151, for matters related to the Exchange Direct Enrollment option for federally-facilitated Exchanges, State-based Exchanges on the Federal platform, and State Exchanges.

Carly Rhyne, (301) 492–4188, or Aziz Sandhu, (301) 492–4437, for matters related to the annual open enrollment period.

Carolyn Kraemer, (301) 492–4197, for matters related to special enrollment periods for Exchange enrollment under parts 147 and 155.

Nikolas Berkobien, (301) 492–4400, for matters related to standardized options.

Aaron Franz, (410) 786–8027, for matters related to user fees.

Rebecca Bucchieri, (301) 492–4341, for matters related to provision of essential health benefits and separate billing and segregation of funds for abortion services.

Erika Melman, (301) 492–4348, Deborah Hunter, (410) 786–0625, or Emily Martin, (301) 492–4400, for matters related to network adequacy.

Lina Rashid, (202) 260–6098, Michelle Koltov, (301) 492–4225, or Kimberly Koch, (202) 622–0854, for matters related to section 1332 waivers.

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I. Executive Summary

American Health Benefit Exchanges, or “Exchanges,” are entities established under the Patient Protection and Affordable Care Act (ACA)¹ through which qualified individuals and qualified employers can purchase comprehensive health insurance coverage through QHPs. Many individuals who enroll in QHPs through individual market Exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums and to receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services. This rule finalizes policies designed to promote greater access to comprehensive health insurance coverage through the Exchanges, consistent with applicable law and with the administration's policy priorities detailed in recent Presidential executive orders.

On January 28, 2021, President Biden issued Executive Order 14009, “Executive Order on Strengthening Medicaid and the Affordable Care Act” (E.O. 14009), which stated the Administration's policy to protect and strengthen the ACA and to make high-quality health care accessible and affordable for every American.² This Executive Order instructed the Secretary of Health and Human Services (hereinafter referred to as “the Secretary” or the “Secretary of HHS”), along with the Secretaries of the Departments of Labor and the Treasury, to review all existing regulations, guidance documents, and other agency actions to determine whether they are consistent with the aforementioned policy, and to consider whether to suspend, revise, or rescind any agency actions that are inconsistent with it.

On January 20, 2021, President Biden issued Executive Order 13985, “On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” (E.O. 13985),³ directing that as a policy matter, the

¹ The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Healthcare 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 proposed rule, HHS refers to the two statutes collectively as the “Affordable Care Act” or “ACA.”

² 86 FR 7793 (Feb. 2, 2021).

³ 86 FR 7009 (Jan. 25, 2021).

Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. E.O. 13985 also directs HHS to assess whether, and to what extent, its programs and policies perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups.

Those who have insurance frequently face barriers to using it because of affordability concerns related to premiums, deductibles, copayments, and coinsurance, as well as challenges related to health literacy and the ability for the insured to find and access in-network providers. These barriers to using insurance are particularly problematic for those with chronic conditions and individuals with social risk factors (such as poverty, minority race and/or ethnicity, social isolation, and limited community resources),⁴ which also includes members of underserved communities, people of color, and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Today, of the 30 million uninsured, half are people of color.⁵ The COVID-19 public health emergency (PHE) has highlighted the negative effects of these circumstances as COVID-19 has unequally affected many racial and ethnic minority groups, putting them more at risk of getting sick and dying from COVID-19.⁶

As part of its review of regulations and policies under the Executive Orders described in the preceding paragraphs, HHS analyzed whether certain policies and requirements addressed in this final rule are consistent with policy goals outlined in the Executive Orders, including whether they might create or perpetuate systemic barriers to obtaining health insurance coverage. The results of HHS's analyses led to the policies and rules finalized in this rule.

In previous rulemakings, HHS established provisions and parameters to implement many ACA requirements and programs. In this final rule, HHS amends and repeals some of these provisions and parameters, with a focus on making high-quality health care accessible and affordable for consumers. These changes provide consumers greater access to coverage through, for example, greater education and outreach, improved affordability for consumers, reduced administrative burden for issuers and consumers, and improved program integrity. As discussed more fully later in the preamble, each of these measures strengthen the ACA or otherwise promote the policy goals outlined in the Executive Orders described earlier in this preamble.⁷

HHS amends § 147.104(b)(2) to specify that issuers are not required to provide a special enrollment period in the individual market with respect to coverage offered outside of an Exchange to qualifying individuals who would be eligible for the proposed special enrollment period triggering event at § 155.420(d)(16) described below.

HHS also amends § 155.210(e)(9) to reinstitute previous requirements that Navigators in federally-facilitated Exchanges (FFE) be required to provide consumers with information and assistance on certain post-enrollment topics, such as the Exchange eligibility appeals process, the Exchange-related components of the PTC reconciliation process, and the basic concepts and rights of health coverage and how to use it.

HHS also finalizes the removal of § 155.221(j) and repeal of the Exchange Direct Enrollment option which established a process for State Exchanges, State-based Exchanges on the Federal platform (SBE-FPs), and FFEs to work directly with private sector entities (including QHP issuers, web-brokers, and agents and brokers) to operate enrollment websites through which consumers can apply for coverage, receive an eligibility determination from the Exchange, and purchase an individual market QHP offered through the Exchange with APTC and cost-sharing reductions (CSRs), if otherwise eligible.

For the 2022 coverage year and beyond, HHS amends § 155.410(e) to lengthen the annual open enrollment period for coverage through all

individual market Exchanges to November 1 through January 15, as compared to the current annual open enrollment period of November 1 through December 15, and HHS codifies flexibility for State Exchanges that operate their own eligibility and enrollment platform to set annual open enrollment period end dates no earlier than December 15.

HHS adds a new paragraph at § 155.420(d)(16) to establish a monthly special enrollment period for qualified individuals or enrollees, or the dependents of a qualified individual or enrollee, who are eligible for APTC and whose household income does not exceed 150 percent of the Federal poverty line (FPL), in order to provide low-income individuals who generally will have access to a premium-free silver plan with a 94 percent actuarial value (AV) with more opportunities to enroll in coverage. This monthly special enrollment period will be available during periods of time when APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the American Rescue Plan Act of 2021 (Pub. L. 117-2) (ARP). HHS also clarifies, for purposes of the special enrollment periods provided at § 155.420(d), that a qualified individual who meets the criteria at § 155.305(f), but who qualifies for a maximum APTC amount of zero dollars, is not considered APTC eligible. This approach will ensure that § 155.420 reflects appropriate special enrollment period eligibility for qualifying individuals who qualify for a maximum APTC amount of zero dollars and for those who become eligible for APTC amounts greater than zero.

In addition, to reflect updated analysis of enrollment and the cost of expanded services offered through the Federal platform, HHS is finalizing the 2022 user fee rate at 2.75 percent of total monthly premiums charged by the issuer for each policy under plans offered through an FFE, and 2.25 percent of the total monthly premiums charged by the issuer for each policy under plans offered through an SBE-FP (rather than 2.25 and 1.75 percent of the total monthly premiums charged by the issuer for each policy under plans offered through an FFE or SBE-FP, respectively, as finalized in the HHS Notice of Benefit and Payment Parameters for 2022 (hereinafter referred to as "part 1 of the 2022 Payment Notice final rule").⁸ These finalized 2022 user

⁴ See "Social Risk Factors and Medicare's Value-Based Purchasing Programs," HHS Office of the Secretary of Planning and Evaluation, available at <https://aspe.hhs.gov/social-risk-factors-and-medicare-value-based-purchasing-programs>.

⁵ "Health Insurance Coverage: Early Release of Estimates From the National Health Interview Survey, January–June 2020," National Center for Health Statistics, February 2021, available at <https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur202102-508.pdf>.

⁶ See Centers for Disease Control and Prevention, "Health Equity Considerations and Racial and Ethnic Minority Groups," updated April 19, 2021, available at <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html#print>, <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html#print>.

⁷ Although many of the policies in this rule support the goals outlined in recent Executive Orders, as described later in the preamble discussions related to individual provisions, each of the provisions is supported by statutory authority independent of the Executive Orders.

⁸ 86 FR 6138.

fee rates are still less than the 2021 user fees currently being collected—3.0 and 2.5 percent of the total monthly premiums charged by the issuer for each policy under plans offered through an FFE or SBE-FP, respectively.

HHS is also finalizing a technical amendment to requirements at § 156.115(a)(3) pertaining to the provision of the essential health benefits (EHB), to include a cross-reference to the Public Health Service (PHS) Act to make clear that health plans subject to EHB requirements must comply with all of the requirements under Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), including any amendments to MHPAEA.

HHS is repealing the separate billing regulation at § 156.280(e)(2), which requires individual market QHP issuers that offer coverage of abortion services for which Federal funds are prohibited⁹ to separately bill for this portion of the policy holder's premium and to instruct the policy holder to pay for the separate bill in a separate transaction. Specifically, HHS will revert to, finalize, and codify the policy finalized in the 2016 Payment Notice¹⁰ such that QHP issuers offering coverage of abortion services for which Federal funds are prohibited again have flexibility in selecting a method to comply with the separate payment requirement in section 1303 of the ACA. As finalized, individual market QHP issuers covering abortion services for which Federal funds are prohibited would still be expected to comply with all statutory requirements in section 1303 of the ACA and all applicable regulatory requirements codified at § 156.280.

This rulemaking also finalizes modifications to the section 1332 Waivers for State Innovation (referred to throughout this rule as section 1332 waivers) implementing regulations, including changes to many of the policies and interpretations of the statutory guardrails recently codified in regulation. The policies and interpretations finalized in this rule supersede and rescind those outlined in the October 2018 "State Relief and Empowerment Waivers" guidance¹¹ (hereinafter referred to as the "2018 Guidance") and repeal the previous codification of the interpretations of the statutory guardrails in part 1 of the 2022 Payment Notice final rule.¹² HHS and the Department of the Treasury

(collectively, the Departments) are also finalizing flexibilities in the public notice requirements and post award public participation requirements for section 1332 waivers under certain future emergent situations. The Departments are also finalizing the processes and procedures for amendments and extensions for approved waiver plans.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the PHS Act to establish various reforms to the group and individual health insurance markets. These provisions of the PHS Act were later augmented by other laws, including the ACA. Subtitles A and C of title I of the ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans¹³ and health insurance issuers in the group and individual markets. The term "group health plan" includes both insured and self-insured group health plans.

Section 2702 of the PHS Act, as added by the ACA, establishes requirements for guaranteed availability of coverage in the group and individual markets.¹⁴

Section 1301(a)(1)(B) of the ACA directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the ACA, including coverage of the services described in section 1302(b) of the ACA, adherence to the cost-sharing limits described in section 1302(c) of the ACA, and meeting the AV levels established in section 1302(d) of the ACA. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the requirement to cover 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 ACA.

Section 1302 of the ACA provides for the establishment of an EHB package

that includes coverage of EHBs (as defined by the Secretary), cost-sharing limits, and AV requirements. Section 1302(b) of the ACA 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 1302(d) of the ACA describes the various levels of coverage based on their AV. Consistent with section 1302(d)(2)(A) of the ACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the ACA directs the Secretary to develop guidelines that allow for *de minimis* variation in AV calculations.

Section 1303 of the ACA, as implemented in 45 CFR 156.280, specifies standards for issuers of QHPs through the Exchanges that cover abortion services for which Federal funding is prohibited. The statute and regulation establish that, unless otherwise prohibited by state law, a QHP issuer may elect to cover such abortion services. If an issuer elects to cover such services under a QHP sold through an individual market Exchange, the issuer must take certain steps to ensure that no PTC or CSR funds are used to pay for abortion services for which public funding is prohibited.

As specified in section 1303(b)(2) of the ACA, one such step is that individual market Exchange issuers must determine the amount of, and collect, from each enrollee, a separate payment for an amount equal to the AV of the coverage for abortions for which public funding is prohibited, which must be no less than \$1 per enrollee, per month. QHP issuers must also segregate funds collected through this payment for abortion services for which Federal funds are prohibited into a separate allocation account used to pay for such abortion services.

Sections 1311(b) and 1321(b) of the ACA provide that each state has the opportunity to establish an individual market Exchange that facilitates the purchase of insurance coverage by qualified individuals through QHPs and meets other standards specified in the ACA. Section 1321(c)(1) of the ACA directs the Secretary to establish and

⁹ These abortion services refer to abortion coverage that is subject to the Hyde Amendment's funding limitations which prohibit the use of Federal funds for such coverage.

¹⁰ 80 FR 10750 (Feb. 27, 2015).

¹¹ 83 FR 53575.

¹² 86 FR 6138.

¹³ The term "group health plan" is used in title XXVII of the PHS Act and is distinct from the term "health plan" as used in other provisions of title I of the ACA. The term "health plan" does not include self-insured group health plans.

¹⁴ Before enactment of the ACA, HIPAA amended the PHS Act (formerly section 2711) to generally require guaranteed availability of coverage for employers in the small group market.

operate such Exchange within states that do not elect to establish an Exchange or, as determined by the Secretary on or before January 1, 2013, will not have an Exchange operable by January 1, 2014.

Section 1311(c)(1) of the ACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs, including network adequacy standards at section 1311(c)(1)(B) of the ACA. Section 1311(d) of the ACA describes the minimum functions of an Exchange. Section 1311(e)(1) of the ACA grants the Exchange the authority to certify a health plan as a QHP if the health plan meets the Secretary's requirements for certification issued under section 1311(c)(1) of the ACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the state. Section 1311(c)(6) of the ACA establishes authority for the Secretary to require Exchanges to provide enrollment periods, including special enrollment periods, including the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act, per section 1311(c)(6)(D) of the ACA.

Sections 1311(d)(4)(K) and 1311(i) of the ACA require each Exchange to establish a Navigator program under which it awards grants to entities to carry out certain Navigator duties.

Section 1312(c) of the ACA generally requires a health insurance issuer to consider all enrollees in all health plans (except 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 and small group market risk pools under section 1312(c)(3) of the ACA.

Section 1312(e) of the ACA 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.

Sections 1313 and 1321 of the ACA 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 ACA provides for state flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a)(1) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA for, among other things, the establishment and operation of Exchanges. When operating an FFE under section 1321(c)(1) of the ACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the ACA to collect and spend user fees. Office of Management and Budget (OMB) Circular A–25 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(d) of the ACA provides that nothing in title I of the ACA must be construed to preempt any state law that does not prevent the application of title I of the ACA. Section 1311(k) of the ACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1332 of the ACA provides the Secretary of HHS and the Secretary of the Treasury (collectively, the Secretaries) with the discretion to approve a state's proposal to waive specific provisions of the ACA, provided the state's section 1332 waiver plan meets certain requirements. Section 1332(a)(4)(B) of the ACA requires the Secretaries to issue regulations regarding procedures for section 1332 waivers.

Section 1402 of the ACA provides for, among other things, reductions in cost sharing for EHB for qualified low- and moderate-income enrollees in silver level QHPs 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 1411(c) of the ACA requires the Secretary to submit certain information provided by applicants under section 1411(b) of the ACA to other Federal officials for verification, including income and family size information to the Secretary of the Treasury.

Section 1411(d) of the ACA provides that the Secretary must verify the accuracy of information provided by applicants under section 1411(b) of the ACA for which section 1411(c) of the ACA does not prescribe a specific verification procedure, in such manner as the Secretary determines appropriate.

Section 1411(f) of the ACA requires the Secretary, in consultation with the Secretary of the Treasury, the Secretary of Homeland Security, and the Commissioner of Social Security, to

establish procedures for hearing and making decisions governing appeals of Exchange eligibility determinations.

Section 1411(f)(1)(B) of the ACA requires the Secretary to establish procedures to redetermine eligibility on a periodic basis, in appropriate circumstances, including eligibility to purchase a QHP through the Exchange and for APTC and CSRs.

Section 1411(g) of the ACA allows the use or disclosure of applicant information only for the limited purposes of, and to the extent necessary to, ensure the efficient operation of the Exchange, including by verifying eligibility to enroll through the Exchange and for APTC and CSRs.

Section 5000A of the Internal Revenue Code ("the Code"), as added by section 1501(b) of the ACA, requires individuals to have minimum essential coverage (MEC) for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act (Pub. L. 115–97, December 22, 2017) the individual shared responsibility payment has been reduced to \$0, effective for months beginning after December 31, 2018. Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals age 30 and above qualify to enroll in catastrophic coverage under 45 CFR 155.305(h) or 156.155.

1. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37031), HHS 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). In the December 27, 2019 **Federal Register** (84 FR 71674), HHS published a final rule that revised standards relating to oversight of Exchanges established by states and periodic data matching frequency. It also added new requirements for certain issuers related to the separate billing and collection of the separate payment for the premium portion attributable to coverage for certain abortion services. In the May 8, 2020 **Federal Register** (85 FR 27550), HHS published the Medicare and Medicaid Programs, Basic Health Programs and Exchanges interim final rule with public comment ("May 2020 IFC") and postponed the

implementation deadline for those separate billing and collection requirements by 60 days. In light of court rulings in the ongoing litigation in Federal courts in Maryland, Washington, and California challenging the separate billing regulation,¹⁵ the separate billing policy is not currently in effect.

2. Market Rules

An interim final rule relating to the HIPAA health insurance reforms was published in the April 8, 1997 **Federal Register** (62 FR 16894). A proposed rule relating to ACA health insurance market reforms that became effective in 2014 was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing those provisions 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 guaranteed renewability. In the Market Stabilization final rule that was published in the April 18, 2017 **Federal Register** (82 FR 18346), HHS released further guidance related to guaranteed availability. In the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 17058), HHS clarified that certain exceptions to the special enrollment periods only apply with respect to coverage offered outside of the Exchange in the individual market.

In the 2022 Payment Notice final rule in the May 5, 2021 **Federal Register** (86 FR 24140) (hereinafter referred to as the “part 2 of the 2022 Payment Notice final rule”), HHS made additional amendments to the guaranteed availability regulation regarding special enrollment periods and finalized new special enrollment periods related to untimely notice of triggering events, cessation of employer contributions or government subsidies to COBRA

continuation coverage, and loss of APTC eligibility.

3. Exchanges

HHS published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). HHS issued initial guidance to states on Exchanges on November 18, 2010. In the July 15, 2011 **Federal Register** (76 FR 41865), HHS published a proposed rule with proposals 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 Small Business Health Options Program (SHOP), eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges, including minimum network adequacy requirements, was published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule).

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), HHS set forth standards related to Exchange user fees. HHS 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 the 2016 Payment Notice in the February 27, 2015 **Federal Register** (80 FR 10750), HHS finalized changes related to network adequacy and provider directories.

In the 2017 Payment Notice in the March 8, 2016 **Federal Register** (81 FR 12203), HHS finalized six standardized plan options to simplify the plan selection process for consumers on the Exchanges and codified SBE-FPs along with relevant requirements, including the associated user fee. In the 2017 Payment Notice, HHS also finalized policies relating to network adequacy for QHPs on the FFEs. In the May 11, 2016 **Federal Register** (81 FR 29146), HHS published an interim final rule with amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). HHS finalized these amendments in the 2018 Payment Notice final rule, published in the December 22, 2016 **Federal Register** (81 FR 94058). The 2018 Payment Notice also modified the standardized options finalized in the 2017 Payment Notice and included three new sets of standardized options.

In the April 18, 2017 Market Stabilization final rule **Federal Register** (82 FR 18346), HHS amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), HHS modified parameters around certain special enrollment periods and discontinued the designation of standardized options. In the April 25, 2019 **Federal Register** (84 FR 17454), the final 2020 Payment Notice established a new special enrollment period. In the May 14, 2020 **Federal Register** (85 FR 29204), the 2021 Payment Notice final rule made certain changes to plan category limitations and special enrollment period coverage effective date rules, allowed individuals provided a non-calendar year qualified small employer health reimbursement arrangement (QSEHRA) to qualify for an existing special enrollment period, and discussed plans for future rulemaking for employer-sponsored coverage (ESC) verification and non-enforcement discretion for Exchanges that do not conduct random sampling to verify whether an employer offers ESC until plan year 2021.

In part 1 of the 2022 Payment Notice final rule, published in the January 19, 2021 **Federal Register** (86 FR 6138), HHS finalized a new Exchange Direct Enrollment (DE) option. In part 2 of the 2022 Payment Notice final rule in the May 5, 2021 **Federal Register** (86 FR 24140) HHS finalized new special enrollment periods related to untimely notice of triggering events, cessation of employer contributions or government subsidies to COBRA continuation coverage, loss of APTC eligibility, and clarified the regulation imposing network adequacy standards with regard to QHPs that do not use provider networks.

4. Essential Health Benefits

On December 16, 2011, HHS released a bulletin¹⁶ that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. A proposed rule relating to EHBs was published in the November 26, 2012 **Federal Register** (77 FR 70643). HHS established requirements relating to EHBs 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

¹⁵ *Washington v. Azar*, 461 F. Supp. 3d 1016 (E.D. Wash. 2020); *Planned Parenthood of Maryland, Inc. v. Azar*, No. CV CCB–20–00361 (D. Md. July 10, 2020); *California v. U.S. Dep’t of Health & Hum. Servs.*, 473 F. Supp. 3d 992 (N.D. Cal. July 20, 2020).

¹⁶ “Essential Health Benefits Bulletin,” December 16, 2011. Available at https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.

FR 12833) (EHB Rule). In the 2019 Payment Notice, published in the April 17, 2018 **Federal Register** (83 FR 16930), HHS added § 156.111 to provide states with additional options from which to select an EHB-benchmark plan for plan years 2020 and beyond.

5. Section 1332 Waivers

In the March 14, 2011 **Federal Register** (76 FR 13553), the Departments published the “Application, Review, and Reporting Process for Waivers for State Innovation” proposed rule to implement section 1332(a)(4)(B) of the ACA. In the February 27, 2012 **Federal Register** (77 FR 11700), the Departments published the “Application, Review, and Reporting Process for Waivers for State Innovation” final rule (hereinafter referred to as the “2012 Final Rule”). In the October 24, 2018 **Federal Register** (83 FR 53575), the Departments issued the 2018 Guidance, which superseded the previous guidance¹⁷ published in the December 16, 2015 **Federal Register** (80 FR 78131) (hereinafter referred to as the “2015 Guidance”), and provided additional information about the requirements that states must meet for waiver proposals, the Secretaries’ application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations. In the November 6, 2020 **Federal Register** (85 FR 71142), the Departments issued an interim final rule (hereinafter referred to as the “November 2020 IFC”), which revises regulations to set forth flexibilities in the public notice requirements and post award public participation requirements for waivers under section 1332 during the COVID-19 PHE. In the December 4, 2020 **Federal Register** (85 FR 78572), the Departments published the “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations” proposed rule (hereinafter referred to as the “2022 Payment Notice proposed rule”) to codify certain policies and interpretations of the 2018 Guidance. In the January 19, 2021 **Federal Register** (86 FR 6138), the Departments published part 1 of the 2022 Payment Notice final rule which codified many of the policies and interpretations outlined in the 2018 Guidance into section 1332 regulations.

B. Stakeholder Consultation and Input

HHS consulted with stakeholders on policies related to the operation of Exchanges relevant to the policies in this final rule. HHS held a number of listening sessions with consumers, providers, employers, health plans, advocacy groups and the actuarial community to gather public input. HHS has solicited input from state representatives on numerous topics, particularly the direct enrollment option for FFEs, SBE-FPs and State Exchanges.

HHS consulted with stakeholders through monthly meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states, and health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. HHS considered all public input it received as HHS developed the policies in this rule.

C. Structure of Final Rule

The regulations outlined in this final rule were proposed in the “Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond Proposed Rule” published in the July 1, 2021 **Federal Register** (86 FR 35156 through 35216) and will be codified in 45 CFR parts 147, 155, and 156. In addition, the regulations outlined in this final rule governing waivers under section 1332 of the ACA at 45 CFR part 155 subpart N will also be codified in 31 CFR part 33.

The changes to part 147 specify that issuers are not required to provide a special enrollment period in the individual market with respect to coverage offered outside of an Exchange to consumers who would be eligible for the special enrollment period at § 155.420(d)(16).

The changes to part 155 repeal the establishment of the Exchange DE option, which established a process for State Exchanges, SBE-FPs, and FFEs to elect to transition to use direct enrollment technology and non-Exchange websites developed by approved web brokers, issuers and other direct enrollment partners to enroll qualified individuals in QHPs offered through the Exchange. HHS is finalizing an extension of the annual individual market open enrollment period to end on January 15 of the applicable year, rather than December 15 of the previous year beginning with the open enrollment period for the 2022 coverage year, and HHS is codifying flexibility for State Exchanges that operate their own eligibility and enrollment platform to

set individual market annual open enrollment period end dates no earlier than December 15 and to adopt accelerated effective dates. HHS is also finalizing the reinstitution of previous requirements that Navigators in FFEs provide consumers with information and assistance on certain post-enrollment topics, such as the Exchange eligibility appeals process, the Exchange-related components of the PTC reconciliation process, and the basic concepts and rights of health coverage and how to use it. HHS is further finalizing the provision of a monthly special enrollment period for qualified individuals or enrollees, or the dependents of a qualified individual or enrollee, who are eligible for APTC and whose household income does not exceed 150 percent of the FPL for periods of time during which enhanced APTC benefits are also available, such that certain applicable taxpayers’ applicable percentage is set at zero, as provided by the section 9661 of the ARP or any subsequent statute or rule. HHS is finalizing a clarification that, for purposes of the special enrollment periods provided at § 155.420(d), a qualified individual, enrollee, or his or her dependent who is eligible for APTC because they meet the criteria at § 155.305(f), but who qualifies for a maximum APTC amount of zero dollars, is not considered APTC eligible for purposes of these special enrollment periods.

The changes to part 156 update the user fee rates for the 2022 benefit year for all issuers participating on the Exchanges using the Federal platform. HHS is also finalizing the repeal of the separate billing requirement, which required individual market QHP issuers that offer coverage for abortion services for which Federal funding is prohibited to separately bill policy holders for the portion of the premium attributable to coverage of such abortion services and instruct the policy holder to pay for this portion of their premium in a separate transaction. Finally, HHS is finalizing an update to cross reference to mental health parity standards in the provision of EHB regulations.

The changes in 31 CFR part 33 and 45 CFR part 155 related to section 1332 waivers rescind the previous incorporation into regulation of certain policies and interpretations announced in the 2018 Guidance and are adopting new policies and interpretations for the statutory guardrails. The Departments are finalizing modifications to the section 1332 implementing regulations, and the proposals related to section 1332 waivers, which include adoption of processes and procedures for

¹⁷ <https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf>.

amendments and extensions for approved waiver plans. Additionally, the Departments are finalizing the extension of certain flexibilities in the public notice requirements and post award public participation requirements for section 1332 waivers during future emergent situations.

III. Provisions of the Updating Payment Parameters and Improving Health Insurance Markets for 2022 and Beyond the Final Rule and Analysis and Responses to Public Comments

In the July 1, 2021 **Federal Register** (86 FR 35156) HHS published the “Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond” proposed rule.¹⁸ HHS received a total of 390 comments, including 168 comments that were substantially similar to one form letter. Comments were received from state entities, such as departments of insurance and State Exchanges, health insurance issuers, providers and provider groups, consumer groups, industry groups, national interest groups, and other stakeholders. The comments ranged from general support for the proposed rule, to specific support of or opposition to the proposed provisions, to specific questions regarding proposed changes. HHS also received a number of comments and suggestions that were outside the scope of the proposed rule. These out-of-scope comments are not addressed in this final rule.

In this final rule, HHS provides a summary of proposed provisions, a summary of the public comments received that directly related to those proposals, its responses to these comments and a description of the provisions HHS is finalizing.

HHS first addresses comments regarding the publication of the proposed rule and the comment period.

Comment: Some commenters were concerned about the length of the comment period, stating that a longer comment period is necessary to allow stakeholders to review the proposed rule and provide thoughtful comments. Some commenters expressed concern that HHS should not calculate the comment period from the posting of the public inspection version, and that HHS would not have time to adequately review and consider all the comments before issuing a final rule.

Response: HHS disagrees that the comment period was not long enough to allow stakeholders to provide meaningful comments. HHS found

commenters’ submissions to be thoughtful and reflective of a detailed review and analysis of the proposed rule. HHS notes that in the interest of providing valuable information for issuers to set their rates for the 2022 plan year as soon as possible, HHS started the 30-day comment period with the posting of the rule for public inspection.

HHS further recognizes the importance of Federal agencies reviewing and considering all the relevant comments before issuing a final rule. The comment period for the proposed rule closed on July 28, 2021. HHS has had ample time to review and fully consider comments relevant to the rules and policies addressed in this final rule.

Comment: HHS received several comments of general support for the rule and for the proposed provisions which expand access to affordable health coverage. Some commenters expressed support for EOs 13985 and 14009. Other commenters expressed concern regarding the timing of the rule and the repeal of policies finalized in part 1 of the 2022 Payment Notice final rule.¹⁹ A few commenters stated that this rule is being published too late in the 2021 plan year for policy implementation and rate-setting for the 2022 plan year.

Response: HHS recognizes that this rulemaking has occurred later than usual in the plan year. However, HHS believes that the policies finalized in this rule align with the goals included in EOs 13985 and 14009.²⁰

While several of the policies in this final rule do not directly impact rate-setting, this final rule is being released prior to the September 21, 2021 deadline for signing final QHP agreements to participate in FFEs and SBE-FPs during the 2022 plan year. The purpose of the policies in this final rule is to strengthen the health insurance markets comprising plans that are subject to the ACA market reforms, and HHS encourages issuers to continue their participation in the Exchanges for 2022. HHS also believes that there is sufficient time to implement the applicable policies in advance of the start of the 2022 plan year.

Comment: One commenter requested that HHS assess and address systemic barriers to access for American Indian and Alaskan Native populations and establish guidance to address the social determinants of health that affect these

communities and other communities of color.

Response: While this comment is outside of the scope of this rule, HHS appreciates this feedback. HHS notes that it is actively seeking ways to engage with stakeholders in an effort to advance health equity and address the social determinants of health that disparately impact communities of color in line with E.O. 13985 as described previously.

A. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Guaranteed Availability of Coverage (§ 147.104)

a. Special Enrollment Periods (§ 147.104(b)(2))

As further discussed in the preamble section regarding the monthly special enrollment period for APTC-eligible qualified individuals with an expected household income no greater than 150 percent of the FPL (§ 155.420(d)(16)), HHS is finalizing the proposed special enrollment period with amendments, so that it is available only during periods of time during which APTC benefits are available such that the applicable taxpayers’ applicable tax percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP. HHS is otherwise finalizing this new special enrollment period as proposed, including adding a new paragraph at § 147.104(b)(2)(i)(G) to specify that issuers are not required to provide this special enrollment period in the individual market with respect to coverage offered outside of an Exchange. HHS proposed to add this paragraph because eligibility for the special enrollment period is based on eligibility for APTC, as discussed in the § 155.420(d)(16) preamble section, and APTC cannot be applied to coverage that is not a QHP offered through an Exchange.²¹ HHS requested comment on this proposal. HHS did not receive many comments on this aspect of the proposed special enrollment period. However, comments that HHS did receive supported the proposal to not require issuers to provide the proposed special enrollment period for consumers to enroll in coverage off-Exchange. HHS appreciates this support and is finalizing the proposed special enrollment period to specify that issuers are not required to provide it in the individual market with respect to coverage offered outside of an Exchange.

¹⁹ 86 FR 24140.

²⁰ See 86 FR 7009 (Jan. 25, 2021) and 86 FR 7793 (Feb. 2, 2021).

²¹ See IRC 36B(b)(2)(A), (c)(2)(A)(i).

¹⁸ 86 FR 35156.

B. Part 155—Exchange Establishment Standards and Other Related Standards under the Affordable Care Act

1. Standardized Options (§ 155.20)

On March 4, 2021, the United States District Court for the District of Maryland decided *City of Columbus v. Cochran*, No. 18–2364, 2021 WL 825973 (D. Md. Mar. 4, 2021). The court reviewed nine separate policies HHS had promulgated in the 2019 Payment Notice final rule. The court vacated four of these policies. One of the policies vacated was the 2019 Payment Notice's cessation of the practice of designating some plans in the FFEs as "standardized options."²² Additionally, in July 2021, President Biden's Executive Order 14036 on Promoting Competition in the American Economy directed HHS to standardize plan options in order to facilitate the plan selection process for consumers on the Exchanges.²³

HHS intends to implement the court's decision as soon as possible, as explained in part 2 of the 2022 Payment Notice final rule.²⁴ HHS will not be able to fully implement those aspects of the court's decision regarding standardized options in time for issuers to design plans and for CMS to be prepared to certify such plans as QHPs for the 2022 plan year. With the rule removing standardized options vacated, HHS will also need to design and propose new standardized options that otherwise meet current market reform requirements.²⁵ HHS will need to design, propose, and finalize such plans in time for issuers to design their own standardized options in accord with HHS's parameters and to submit those plans for approval by applicable regulatory authorities and for certification as QHPs. This is not feasible for the upcoming QHP certification cycle for the 2022 plan year. The plan certification process for that year has already begun as of April 22, 2021. CMS's planning for the QHP certification cycle for the 2022 plan year has taken into account the existing policies that the court vacated, and it is too late now to revisit those factors if the process is to go forward in time for plans to be certified in time for the annual open enrollment period later this year.

Specifically, in the last iteration of standardized options HHS finalized in the 2018 Payment Notice, HHS created three sets of standardized options based on FFE and SBE–FP enrollment data

and state cost-sharing laws. The basis on which HHS created these three sets of options, as well as a number of other factors in the individual market (for example, states with FFEs or SBE–FPs transitioning to State Exchanges), have changed considerably since the last iteration of standardized options in 2018. Further, HHS does not have sufficient time to conduct a full analysis of the changes that have occurred in the last several years necessary to timely design and propose standardized options suitable for the current environment. Additionally, in prior years, HHS proposed and finalized standardized option plan designs prior to the start of the QHP certification cycle for the following plan year such that issuers had sufficient time to assess these standardized options and could thus determine if they wanted to offer them and take the steps necessary to do so. Issuers will not have a sufficient amount of time to meaningfully assess any standardized options HHS would propose and decide whether or not to offer them if such proposals were made effective before the 2023 plan year.

For these reasons, HHS intends to resume the designation of standardized options and to propose specific plan designs in more complete detail in the 2023 Payment Notice. HHS sought the views of stakeholders regarding issues related to the proposal of new standardized options, including the views of states with FFEs or SBE–FPs regarding how unique state cost-sharing laws could affect standardized option plan designs.

The following is a summary of the comments received and HHS's responses related to standardized options.

Comment: Some commenters recommended not requiring issuers to offer standardized options. Some commenters also recommended permitting issuers to voluntarily offer standardized options in states with State Exchanges, including SBE–FPs, even if issuers in the FFEs were required to offer them. Some commenters also noted opposition to limiting the number of non-standardized plans issuers could offer. Some commenters also recommended not preferentially or differentially displaying standardized options on *HealthCare.gov*.

These commenters explained that issuers are already required to cover the EHB at specified metal tiers of coverage, which provides consumers a sufficient degree of standardization. These commenters also explained that requiring issuers to offer standardized options could result in an influx of options that fail to provide additional

value to consumers and make it more difficult to compare plan options. These commenters also explained that limiting the number of non-standardized plans issuers could offer would inhibit innovative plan designs that meet diverse coverage needs. These commenters also explained that the preferential or differential display of standardized options would appear to favor some plans over others, inadvertently steer consumers towards standardized plans, and discourage consumers from exploring all available options. These commenters recommended that CMS identify issuers with a disproportionately high volume of plan options in a given geographic region and work with these issuers to ensure there are actual meaningful differences among the plans.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

Comment: Some commenters recommended that CMS should employ a minimally disruptive approach in designing standardized options and not design plans to be radically different from those currently offered. These commenters explained that such plans would be more complicated for issuers to develop and could be challenging for consumers to interpret. These commenters recommended that CMS offer standardized options that are based on the most popular plans currently offered on the Exchanges, a similar approach to that taken in past iterations. Several of these commenters also recommended that CMS not be overly prescriptive in standardizing every aspect of cost sharing, but instead focus on setting annual deductible and out-of-pocket limits.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

Comment: Some commenters explained that plan standardization could stifle competition. These commenters explained that if cost sharing is standardized, the only difference between plans will be networks. These commenters also explained that if standardization strengthens the importance of networks while deemphasizing other aspects of coverage, issuers may not stay in markets where network costs exceed their competitors'. These commenters further explained that with every additional aspect of coverage that is standardized, issuers will have to consider their ability to compete as

²² See 83 FR 16974–16975.

²³ See 86 FR 36987 (Jul. 9, 2021).

²⁴ See 86 FR 24140, 24264–24265.

²⁵ See 45 CFR 155.220(c)(3)(i)(H).

potential areas to innovate and differentiate are limited.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

Comment: Commenters also expressed support for requiring issuers to offer standardized options, limiting the number of non-standardized plans that issuers could offer, and preferentially or differentially displaying standardized options.

Commenters explained the importance of simplifying the complex process of purchasing insurance and the important role that standardized options could play in that simplification.

Commenters explained that there is significant variation in the cost sharing structures of non-standardized plans, much of which cannot be identified without a detailed analysis of benefit designs. Commenters explained that many individuals do not have the time, resources, or health literacy necessary for this level of analysis. Commenters explained that enrollees typically choose plans based on more readily available comparison points, like premiums, rather than factors that would be illuminated by a more detailed examination of plan designs, like expected out-of-pocket costs. Commenters explained that selecting a plan solely based on its premium without taking into consideration other attributes of its design, such as its cost sharing structure, deductible, or expected out-of-pocket costs, can result in unexpected costs and financial harm for consumers.

Commenters explained that barriers to conducting a detailed analysis of plan designs are particularly pronounced for those whose resources are already severely constrained, including those with limited English proficiency, those with inadequate internet access, and those with complex health needs. Commenters explained that facilitating consumer understanding and streamlining decision-making would benefit these populations as well as populations with disproportionately high rates of chronic diseases.

Commenters also explained that standardized plans could help individuals more easily identify plans that have potentially discriminatory benefit designs, such as plans that have coinsurance subject to the deductible as the cost sharing type for specialty tier prescription drugs. These commenters explained that discriminatory benefit designs target individuals with particular disabilities or health conditions by leaving them with

substantial out-of-pocket costs.

Commenters explained that conditions that are typically targeted, including HIV, diabetes, cancer, and mental health conditions, disproportionately affect individuals of color. Commenters explained that discriminatory benefit designs continue to violate the ACA's protections for people with preexisting conditions and its prohibition on discrimination based on race, sex, and disability.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

Comment: Commenters also recommended taking a more prescriptive approach beyond requiring issuers to offer standardized plans, limiting the number of non-standardized plans, and preferentially or differentially displaying standardized plans. These commenters recommended requiring issuers to offer standardized options exclusively, pointing to Covered California's approach, which has required issuers to offer standardized plans exclusively since 2014. These commenters explained that in Covered California's approach, to the extent issuers want to offer non-standardized products, they need to demonstrate that such designs are also patient-centered. These commenters explained that issuers in California have not seen the value in offering non-standardized options to date, suggesting that California's approach to standardized options has satisfied the needs of issuers and enrollees alike.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

Comment: Commenters also made recommendations regarding specific aspects of standardized plan designs. Some commenters expressed concern about the cost-sharing structure in the first set of standardized plans in the 2018 Payment Notice in particular, which had coinsurance subject to the deductible as the form of cost sharing for occupational, physical, and speech therapies. Many commenters also noted a strong preference for copayments over coinsurance as the form of cost sharing for as many benefit categories as possible. These commenters explained that consumers prefer copayments to coinsurance because copayments are more transparent and make it easier to predict out-of-pocket costs. Commenters also explained that in the context of prescription drugs, the use of coinsurance results in patients paying

cost sharing amounts based on a medicine's list price, rather than a medicine's net price, which accounts for manufacturer discounts and rebates paid to pharmacy benefit managers (PBMs) and issuers. Some commenters recommended that standardized plans include a nominal cost-sharing cap in the form of copayments for all tiers of prescription drug coverage to limit the amount that consumers spend on prescriptions every month, as several states have already done.

Commenters also recommended having low deductibles, explaining that deductibles act as a barrier to access. One commenter pointed to Washington's standardized plans, which have a deductible that is on average \$1,000 less than non-standard offerings and provide more pre-deductible services. Commenters also recommended exempting a range of benefits from the deductible, including primary care visits, specialist visits, outpatient visits, mental health services, habilitative and rehabilitative services, pediatric preventative services, preventative care, chronic condition management, and prescription drug coverage. One commenter explained that any standardized plan that is also a high deductible health plan (HDHP) should provide pre-deductible coverage for preventive care the Internal Revenue Service (IRS) has determined is permitted to be provided without a deductible pursuant to section 223(c)(2)(C) of the Code.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

Comment: One commenter recommended delaying the implementation of standardized options requirements until plan year 2024 to allow issuers sufficient time to prepare for this change.

Response: HHS will take these considerations into account when designing the standardized options that will be proposed in the 2023 Payment Notice.

2. Navigator Program Standards (§ 155.210)

HHS proposed to amend § 155.210(e)(9) to reinstitute the requirement that Navigators in the FFEs provide information and assistance with regard to certain post-enrollment topics.

Sections 1311(d)(4)(K) and 1311(i) of the ACA require each Exchange to establish a Navigator program under which it awards grants to entities to 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; facilitate enrollment in QHPs; provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the PHS Act, or any other appropriate state agency or agencies for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange. The statute also requires the Secretary, in collaboration with states, to develop standards to ensure that information made available by Navigators is fair, accurate, and impartial. HHS has implemented the statutorily required Navigator duties through regulations at §§ 155.210 (for all Exchanges) and 155.215 (for Navigators in FFEs).

Further, section 1311(i)(4) of the ACA requires the Secretary to establish standards for Navigators to ensure that Navigators are qualified, and licensed, if appropriate, to engage in the Navigator activities described in the statute and to avoid conflicts of interest. This provision has been implemented at §§ 155.210(b) (generally for all Exchanges) and 155.215(b) (for Navigators in FFEs).

HHS has also established under § 155.205(d) and (e) that each Exchange must have a consumer assistance function, including the Navigator program, and must conduct outreach and education activities to educate consumers about the Exchange and insurance affordability programs to encourage participation.

HHS proposed to amend § 155.210(e)(9) to reinstitute the requirement that Navigators in the FFEs provide information and assistance with regard to certain post-enrollment topics rather than merely being authorized to do so.

Following a reduction in overall funding available to the FFE Navigator program in 2020, HHS provided more flexibility to FFE Navigators by making the provision of certain types of assistance, including post-enrollment assistance, permissible, but not required, for FFE Navigators under Navigator grants awarded in 2019 or any later year.²⁶ On August 27, 2021, HHS

awarded \$80 million in grant funding to 60 Navigator grantees in 30 states with an FFE for the 2022 plan year.²⁷ With this substantially increased funding for the FFE Navigator program for the 2022 plan year, HHS noted that HHS believes there will be sufficient Navigator grant funding available to support the post-enrollment duties HHS proposed to once again require of FFE Navigators. HHS also noted that HHS believes this proposal aligns with E.O. 14009 on Strengthening Medicaid and the ACA because it will improve consumers' access to health coverage information, not only when selecting a plan, but also throughout the year as they use their coverage.²⁸ In addition, the proposal was designed to ensure that consumers would have access to skilled assistance beyond applying for and enrolling in health insurance coverage through the Exchange, including, for example, assistance with the process of filing Exchange eligibility appeals, understanding basic information about PTC reconciliation, and understanding basic concepts and rights related to health coverage and how to use it, such as locating providers and accessing care.

Section 1311(i)(3)(D) of the ACA and 45 CFR 155.210(e)(4) already expressly require Navigators to provide post-enrollment assistance by referring consumers with complaints, questions, or grievances about their coverage to appropriate state agencies. This suggests that Congress anticipated that consumers would need assistance beyond the application and enrollment process, and that Navigators would maintain relationships with consumers and be a source of such post-enrollment assistance.

Consistent with the requirements under section 1311(i)(3)(B) and (C) of the ACA that Navigators distribute fair and impartial information concerning enrollment in QHPs and facilitate enrollment in QHPs, and pursuant to the Secretary's authority under section 1321(a)(1)(A) of the ACA, HHS proposed to reinstitute as a requirement at § 155.210(e)(9)(i) that Navigators in

the individual shared responsibility payment that are granted through the Exchange; understanding the availability of exemptions from the requirement to maintain MEC and from the individual shared responsibility payment that are claimed through the tax filing process and how to claim them; the Exchange-related components of the PTC reconciliation process; understanding basic concepts and rights related to health coverage and how to use it; and referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice on certain Exchange-related topics.

²⁷ <https://www.cms.gov/newsroom/press-releases/biden-harris-administration-quadruples-number-health-care-navigators-ahead-healthcaregov-open>.

²⁸ 86 FR 7793 (Feb. 2, 2021).

the FFEs must help consumers with understanding the process of filing appeals of Exchange eligibility determinations. HHS noted that HHS was once again not proposing to establish a duty for Navigators to represent a consumer in an appeal, sign an appeal request, or file an appeal on the consumer's behalf. HHS noted that HHS believes that helping consumers understand Exchange appeal rights when they have received an adverse eligibility determination when applying for health insurance coverage, and assisting them with the process of completing and submitting appeal forms, would help to facilitate enrollment through the FFEs and would help consumers obtain fair and impartial information about enrollment through the FFEs. HHS discussed that HHS would interpret the proposal to include helping consumers file appeals of eligibility determinations made by an Exchange related to enrollment in a QHP, special enrollment periods, and any insurance affordability program, including eligibility determinations for Exchange financial assistance, Medicaid, the Children's Health Insurance Program (CHIP), and the Basic Health Program.

Currently, pursuant to § 155.210(e)(9)(ii), Navigators in the FFEs are permitted to provide information and assistance to consumers with regard to understanding and applying for exemptions from the individual shared responsibility payment that are granted through the Exchange, understanding the availability of exemptions from the requirement to maintain minimum essential coverage and from the individual shared responsibility payment that are claimed through the Federal income tax filing process and how to claim them, and understanding the availability of the IRS resources on this topic. HHS proposed to amend § 155.210(e)(9)(ii) slightly to reinstitute as a requirement that Navigators in the FFEs must help consumers understand and apply for exemptions from the requirement to maintain minimum essential coverage granted by the Exchange. Although consumers who do not maintain minimum essential coverage no longer need to receive an exemption from the individual shared responsibility payment to avoid having to make such a payment, Navigators can still assist consumers age 30 or above with filing an exemption to qualify to enroll in catastrophic coverage under § 155.305(h). HHS noted that HHS believes that the proposal was consistent with Navigators' duty under

²⁶ 84 FR 17511–17514 (April 25, 2019). These post-enrollment topics included: Understanding the process of filing Exchange eligibility appeals; understanding and applying for exemptions from

section 1311(i)(3)(B) and (C) of the ACA to distribute fair and impartial information concerning enrollment in QHPs, since impartial information concerning the availability of exemptions for consumers age 30 or above to enroll in catastrophic coverage would help consumers make informed decisions about whether or not to enroll in such coverage. This assistance with Exchange-granted exemptions from the requirement to maintain minimum essential coverage would include informing consumers about the availability of the exemption; helping consumers fill out and submit Exchange-granted exemption applications and obtain any necessary forms prior to or after applying for the exemption; explaining what the exemption certificate number is and how to use it; and helping consumers understand and use the Exchange tool to find catastrophic plans in their area.

In addition, HHS proposed to reinstitute as a requirement at § 155.210(e)(9)(iii) that Navigators must help consumers with the Exchange-related components of the PTC reconciliation process and with understanding the availability of IRS resources on this process. As explained in the proposed rule, this would include ensuring consumers have access to their Forms 1095-A and receive general, high-level information about the purpose of this form that is consistent with published IRS guidance on the topic. The proposal stemmed from the requirement under section 1311(i)(3)(B) of the ACA that Navigators distribute fair and impartial information concerning the availability of the PTC under section 36B of the Code.

Consumers who receive premium assistance through APTC may need help with a variety of issues related to the requirement to reconcile the APTC with the PTC allowed for the year of coverage. As explained in the proposed rule, FFE Navigators would be required to help consumers obtain IRS Form 1095-A, Health Insurance Marketplace Statement, and Form 8962, Premium Tax Credit (PTC), and the instructions for Form 8962, and to provide general information, consistent with applicable IRS guidance, about the significance of the forms. HHS noted that, as proposed, Navigators would also be required to help consumers understand (1) how to report errors on the Form 1095-A; (2) how to find silver plan premiums using the Exchange tool; and (3) the difference between APTC and PTC and the potential implications for enrollment and reenrollment of not filing a tax return and reconciling the APTC paid

on consumers' behalf with their PTC for the year.

HHS noted that, as proposed, Navigators would still not be permitted to provide tax assistance or advice, or interpret tax rules and forms within their capacity as FFE Navigators. However, their expertise related to the consumer-facing aspects of the Exchange, including eligibility and enrollment rules and procedures, would uniquely qualify them to help consumers understand and obtain information from the Exchange that is necessary to understand the PTC reconciliation process. Because the proposal included a requirement that Navigators provide consumers with information and assistance understanding the availability of IRS resources, HHS noted that Navigators would be expected to familiarize themselves with the availability of materials on *irs.gov*, including the Form 8962 instructions, IRS Publication 974, Premium Tax Credit, and relevant FAQs, and to refer consumers with questions about tax law to those resources or to other resources, such as free tax return preparation assistance from the Volunteer Income Tax Assistance or Tax Counseling for the Elderly programs.

To help ensure consumers have seamless access to Exchange-related tax information beyond the basic information that Navigators can provide, HHS proposed to reinstitute as a requirement at § 155.210(e)(9)(v) that FFE Navigators must refer consumers to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about the Exchange application and enrollment process, and PTC reconciliations.²⁹

In the proposed rule, HHS discussed that it interprets the Navigator duties to facilitate enrollment in QHPs in section 1311(i)(3)(C) of the ACA, to distribute fair and impartial information concerning enrollment in QHPs under section 1311(i)(3)(B) of the ACA, and to conduct public education activities to raise awareness about the availability of QHPs in section 1311(i)(3)(A) of the ACA to include helping consumers understand the kinds of decisions they

will need to make in selecting coverage, and how to use their coverage after they are enrolled. HHS has previously stated that one of the overall purposes of consumer assistance programs is to help consumers become fully informed and health literate.³⁰

To improve consumers' health literacy related to coverage generally, and to ensure that individual consumers are able to use their coverage meaningfully, HHS proposed to reinstitute at § 155.210(e)(9)(iv) the requirement that Navigators in the FFEs must help consumers understand basic concepts and rights related to health coverage and how to use it. HHS also proposed to expand its interpretation of this requirement and the activities that fall within the requirement's scope. As explained in the proposed rule, these activities could be supported through the use of existing resources such as the CMS "From Coverage to Care" initiative, which HHS encourages Navigators to review, and which are now available in multiple languages.³¹ HHS noted that, as proposed, the provision would improve consumers' access to health coverage information, not just when selecting a plan, but also when using their coverage.

HHS noted that HHS believes expanding its interpretation of the requirement that Navigators help consumers understand basic concepts and rights related to health coverage and how to use it and the activities that fall within the scope of this requirement is vital to improving health equity and helping to address social determinants of health, particularly among underserved and vulnerable populations.³² Navigators are already required under § 155.210(e)(8) to provide targeted assistance to underserved or vulnerable populations. Underserved and vulnerable populations often experience lower levels of health literacy, which can be a barrier to enrolling in and accessing care.³³ Social determinants of health can also create significant disparities in whether and how an individual is able to afford and access health coverage and health care services, including primary and preventive care. As trusted partners and members of local communities, HHS noted that Navigators are uniquely positioned to establish and build trust

²⁹ HHS notes that HHS did not propose to reinstitute at § 155.210(e)(9)(v) the requirement that Navigators must provide referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about exemptions from the requirement to maintain MEC and from the individual shared responsibility payment in light of the fact that the individual shared responsibility payment was reduced to zero for months beginning after December 31, 2018 under the Tax Cuts and Jobs Act (Pub. L. 115-97, December 22, 2017).

³⁰ See 79 FR 30276.

³¹ See <https://marketplace.cms.gov/c2c>.

³² 86 FR 7009 (Jan. 25, 2021).

³³ Access to Health Services: Healthy People 2020. Office of Disease Prevention and Health Promotion, Department of Health & Human Services. <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/access-to-health>.

with individuals and families as they transition from enrolling in health coverage to using and maintaining their coverage throughout the year.

Additionally, HHS noted that Navigators in FFEs are already required under § 155.215(c)(1) to develop and maintain general knowledge about the racial, ethnic, and cultural groups in their service area, including each group's health literacy and other needs, and under § 155.215(c)(2) to collect and maintain updated information to help understand the composition of the communities in the service area. Because the health literacy needs of consumers will vary depending on their circumstances, HHS noted that HHS is not requiring Navigators to help consumers with specific health literacy topics. Instead, HHS proposed to expand its interpretation of the Navigator duties to be reinstituted as requirements at § 155.210(e)(9)(iv) to include, for example, helping consumers understand (1) key terms used in health coverage materials, such as "deductible" and "coinsurance," and how they relate to the consumer's health plan; (2) the cost and care differences between a visit to the emergency department and a visit to a primary care provider under the coverage options available to the consumer; (3) how to evaluate their health care options and make cost-conscious decisions, including through the use of information required to be disclosed by their health plan as a result of the Transparency in Coverage Final Rules;³⁴ (4) how to identify in-network providers to make and prepare for an appointment with a provider—including utilizing tools and resources available through the No Surprises Act³⁵ to make informed decisions about their care; (5) how the consumer's coverage addresses steps that often are taken after an appointment with a provider, such as making a follow-up appointment and filling a prescription; and (6) the right to coverage of certain preventive health services without cost sharing under QHPs—including information and resources related to accessing viral testing and vaccination options supported by Exchange coverage. HHS noted that, if this proposal were finalized, CMS intends to make training materials and other educational resources available to Navigators regarding the proposed

expanded interpretation of this requirement.

HHS noted that, as proposed, FFE Navigators would continue to be permitted to perform the Navigator duties specified in § 155.210(e)(9) until this provision, if finalized, became effective. HHS explained that if the proposal was finalized, FFE Navigators would be required to perform the Navigator duties specified in § 155.210(e)(9) beginning with Navigator grants awarded after the effective date of this rule, including non-competing continuation awards. For example, if the proposal was finalized prior to Navigator grant funding being awarded in fiscal year (FY) 2022, FY 2021 Navigator grantees would be required to perform these duties beginning with the Navigator grant funding awarded in FY 2022 for the second 12-month budget period of the 36-month period of performance. To the extent FFE Navigators awarded grant funding in FY 2021 are not already performing these duties under their year one project plans when the provision, if finalized, becomes effective, HHS noted that they can revise their project plans to incorporate performance of the duties specified in § 155.210(e)(9) as part of their non-competing continuation application for their FY 2022 funding. HHS also noted that if the provision was finalized as proposed, HHS would codify in § 155.210(e)(9) the applicability date to make clear when the Navigator duties specified in § 155.210(e)(9) would once again be required.

HHS discussed in the proposed rule that HHS interprets the requirement to facilitate enrollment in a QHP under section 1311(i)(3)(C) of the ACA, and the requirement at § 155.210(e)(2) to provide information that assists consumers with submitting the eligibility application, to include assistance with updating an application for coverage through an Exchange, including reporting changes in circumstances and assisting with submitting information for eligibility redeterminations. Additionally, HHS noted that Navigators are already permitted, but not required, to help with a variety of other post-enrollment issues. For example, HHS noted that HHS interpreted the requirements in § 155.210(e)(1) and (2) that Navigators conduct public education activities to raise awareness about the Exchange and provide fair and impartial information about the application and plan selection process to mean that Navigators may educate consumers about their rights with respect to coverage available through an Exchange, such as

nondiscrimination protections, prohibitions on preexisting condition exclusions, and preventive services available without cost-sharing. HHS also noted that HHS interpreted these requirements, together with the requirement in section 1311(i)(3)(B) of the ACA that Navigators distribute fair and impartial information concerning enrollment in QHPs, and the availability of Exchange financial assistance, to mean that Navigators may assist consumers with questions about paying premiums for coverage or insurance affordability programs enrolled in through an Exchange. Finally, HHS noted that HHS interpreted the requirement in section 1311(i)(3)(D) of the ACA and § 155.210(e)(4) to provide referrals for certain post-enrollment issues to mean that Navigators may help consumers obtain assistance with coverage claims denials.

Certified application counselors (CACs) do not receive grants from the FFEs, and thus may have more limited resources than Navigators. As a result, while HHS did not propose to require CACs to further expand their required duties, HHS noted that HHS encouraged CACs to help with activities consistent with their existing regulatory duties and recognized that many of these CACs may already be participating in these post-enrollment activities.

The following is a summary of the comments received and HHS's responses related to Navigator program standards at § 155.210.

Comment: The vast majority of comments HHS received in relation to this proposal expressed enthusiastic support. Many commenters stated that they believe it is important that high-quality consumer assistance to help people find, keep, and use health coverage be free and widely available. Several commenters emphasized that this was particularly important for individuals with limited English proficiency (LEP) or those who lack basic health insurance literacy to reduce health disparities in rural and underserved communities, including the Black, Indigenous, and other People of Color (BIPOC) community. Additionally, several commenters supported and noted the importance of increased funding for the Navigator program.

Response: HHS appreciates the comments in support of this proposal and is finalizing the proposal to amend § 155.210(e)(9) to reinstitute the requirement that Navigators in the FFEs provide information and assistance with regard to certain post-enrollment topics as proposed. HHS also appreciates commenters' support of increased

³⁴ 85 FR 72158.

³⁵ Title I of Division BB of the Consolidated Appropriations Act, 2021, Pub. L. 116–260 (Dec. 27, 2020).

funding for the Navigator program, which has funded 60 Navigator grantees in 30 FFE states for plan year 2022.

Comment: A few commenters said they believe the proposed Navigator duties duplicate services provided by issuers or agents and brokers. A few commenters suggested that Navigators be required to be licensed, carry errors and omissions insurance, and be under the oversight of state regulators.

Response: HHS believes it is important for consumers to have access to a variety of assistance options. HHS especially believes it is important that consumers have access to Navigators who, unlike agents and brokers, are required under § 155.210(e)(2) to provide information and services in a fair, accurate, and impartial manner, and to abide by the conflict of interest provision at § 155.210(d)(4) prohibiting Navigators from receiving any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or a non-QHP. Although they are not required by CMS to carry errors and omissions insurance, Navigators are required to complete HHS-approved training, achieve a passing score on all approved certification examinations, and be certified or recertified on at least an annual basis before carrying out any consumer assistance functions under § 155.210. Additionally, Navigators in all states are required under § 155.210(c)(1)(iii) to meet any licensing, certification, or other standards prescribed by the state or Exchange, if applicable, so long as the standards do not prevent the application of the provisions of title I of the ACA.

Comment: A few commenters expressed concern that CMS did not propose to restore the requirements to have at least two in-person Navigator organizations in each state and to ensure that at least one of those organizations was a community and consumer-focused nonprofit group.

Response: HHS recognizes that trusted community non-profits and in-person presence are desirable qualities for Navigator organizations, and that these can be particularly valuable in serving vulnerable populations such as minorities, individuals with LEP, and individuals with disabilities. However, the existing Navigator grant process already gives considerable weight to the capacity of the Navigator organization to serve vulnerable populations, including those who may need communications assistance, lack broadband access, or have specialized needs. Therefore, HHS believes that reinstating these

requirements would not be beneficial to Exchanges, as they currently have the flexibility to award funding to the number and type of entities that will be most effective for the specific Exchange, thus optimizing use of the funding amounts available to direct investments to effective and efficient Navigators, which may include selecting a single, high performing grantee in an Exchange.

Additionally, reinstating 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 to have only one Navigator grantee, and where the strongest applicant is not a community and consumer-focused nonprofit group. Reinstating 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 and would limit an Exchange's ability to target to the highest scoring and performing entities, regardless of organization type.

Comment: A few commenters suggested HHS reinstate the requirement that Navigators receiving grants maintain a physical presence in the Exchange service area.

Response: HHS agrees 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. HHS believes that entities with a physical presence and strong relationships in their FFE service areas tend to deliver the most effective outreach and enrollment results. Navigator grant applicants that demonstrate the ability to maintain these relationships and establish new relationships through a physical presence in their proposed service area(s) may receive a higher score on their application than those who do not. The majority of HHS's 2021 Navigator grantees will be maintaining a physical presence in the state they are serving, and there will be at least one physically present Navigator organization in every FFE state. Additionally, 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 underserved 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 the ACA and § 155.210(c)(1)(ii).

After consideration of the comments received, HHS is finalizing the proposals as proposed. FFE Navigators will continue to be permitted to perform the Navigator duties specified in § 155.210(e)(9) until Navigator grants are awarded in 2022. FFE Navigators will be required to perform the Navigator duties specified in § 155.210(e)(9) beginning with Navigator grants awarded in 2022, including non-competing continuation awards. Thus, prior to Navigator grant funding being awarded in FY 2022, FY 2021 Navigator grantees will be required to perform these duties beginning with the Navigator grant funding awarded in FY 2022 for the second 12-month budget period of the 36-month period of performance.

3. Exchange Direct Enrollment Option (§ 155.221(j))

In part 1 of the 2022 Payment Notice final rule, HHS codified § 155.221(j), which established a process for states to elect a new Exchange Direct Enrollment option (Exchange DE option). Under the Exchange DE option, State Exchanges, SBE-FPs, and FFE states may work directly with private sector entities (including QHP issuers, web-brokers, and agents and brokers) to transition to private-sector enrollment pathways through which consumers can apply for coverage, receive an eligibility determination from the Exchange, and purchase an individual market QHP offered through the Exchange with APTC and CSRs, if otherwise eligible. These private-sector pathways could be offered in addition to or instead of a centralized eligibility and enrollment website operated by an Exchange. Subject to meeting HHS approval requirements under § 155.221(j)(1) and (2), the Exchange DE option may be implemented in states with a State Exchange beginning in plan year 2022 and in SBE-FP or FFE states beginning in plan year 2023. HHS also finalized a 2023 user fee rate of 1.5 percent of the total monthly premiums charged by issuers for each policy in FFE and SBE-FP states that elect the Exchange DE option. Since the publication of part 1 of the 2022 Payment Notice final rule, there have been significant changes to policy and operational priorities, as well as the enactment of new Federal laws. Given these changes, as well as a general lack of interest expressed by states in the option, and potential for the Exchange DE option to be misaligned with administration priorities, HHS proposed to remove § 155.221(j) and repeal the Exchange DE option.

On January 20, 2021, President Biden issued the E.O. 13985,³⁶ directing that as a policy matter the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. On January 28, 2021, President Biden issued E.O. 14009.³⁷ Section 3 of E.O. 14009 directs HHS, and the heads of all other executive departments and agencies with authorities and responsibilities related to Medicaid and the ACA, to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether they are inconsistent with policy priorities described in Section 1 of E.O. 14009, to include protecting and strengthening the ACA by assisting people who are potentially eligible for coverage, and eliminating unnecessary difficulties to obtaining health insurance. Specifically, this agency review must evaluate whether existing policies or regulations, “. . . undermine the Health Insurance Marketplace®³⁸ or the individual, small group, or large group markets for health insurance . . .” or “. . . present unnecessary barriers to individuals and families attempting to access Medicaid or ACA coverage . . .”³⁹

Section 2 of E.O. 14009 also requires that the Secretary of HHS consider whether to implement an Exchange special enrollment period for exceptional circumstances pursuant to § 155.420(d)(9) and other existing authorities, for uninsured and underinsured individuals to obtain coverage in light of the special circumstances caused by the COVID-19 pandemic. After E.O. 14009 was issued, HHS used its discretion to make such a special enrollment period available to uninsured and underinsured consumers through *HealthCare.gov* from February 15, 2021, through May 15, 2021. To support outreach, education and enrollment efforts for this special enrollment period, HHS has provided \$2.3 million in additional funding to current Navigator grantees in the FFEs.⁴⁰

All State Exchanges followed suit and implemented corresponding special

enrollment periods on similar timelines. HHS later made a decision to extend the ability of consumers to access the special enrollment period through *HealthCare.gov* through August 15, 2021, and many State Exchanges extended their special enrollment periods, as well. As of August 10, 2021, 2.5 million consumers have enrolled in coverage through *HealthCare.gov* and the State Exchanges, which represents a substantial increase from previous years when special enrollment periods were available primarily for normal qualifying life events.⁴¹

In addition, Congress recently passed the ARP,⁴² which was signed into law on March 11, 2021. The ARP establishes new ACA programs, including a new grant program for Exchange modernization, which appropriates \$20,000,000 in Federal funding, which is available until September 30, 2022, to State Exchanges to implement Exchange system, program, or technology updates to ensure compliance with applicable Federal requirements. It also modifies eligibility criteria for existing ACA programs. For example, the provisions in the ARP include a temporary change (for taxable years 2021 and 2022) that allows consumers with household income above 400 percent of the FPL to be applicable taxpayers potentially eligible for PTC, an update to applicable percentage tables to increase the amount of PTC for qualified individuals in all income brackets, and a modification of eligibility for PTC for consumers receiving, or approved to receive, unemployment compensation in 2021. Beginning on April 1, HHS operationalized these new requirements through *HealthCare.gov*, and is providing technical assistance to State Exchanges that are operationalizing these requirements at the state level. The approximately 2.5 million consumers that have enrolled in coverage through *HealthCare.gov* and the State Exchanges during the COVID-19 special enrollment period have reduced their monthly premiums by \$40 per person per month due to the ARP's premium credits, with more than one-third of consumers finding coverage for \$10 or less per month. In addition, out-of-pockets costs have fallen for new consumers that have enrolled since April, with the median plan deductible falling by nearly 90 percent from \$450 to \$50.⁴³

There are also new obligations established via other health care-related legislation for which HHS is responsible to implement in coordination with states and other Federal Departments. This includes the No Surprises Act,⁴⁴ which was enacted on December 27, 2020, and establishes an extensive array of Federal and state requirements and programs to protect consumers against surprise medical bills.

Given its obligation to review all existing policies and regulations in line with E.O. 14009, E.O. 13985, and recent actions by Congress, including the health care-related provisions of the ARP and other new Federal legislation, for which HHS is now responsible or centrally involved in implementing, HHS determined that all available resources should be directed to ensuring HHS is able to efficiently and effectively meet those obligations. Permitting the establishment of the Exchange DE option would detract from those efforts. Furthermore, meeting the new requirements of the health care provisions of the ARP would add complexity to Exchange operations that could reduce the prospects for successful implementation of the Exchange DE option, even if temporarily. For instance, states and DE entities would need to coordinate and implement new procedures to ensure that consumers receive eligibility determinations and are enrolled in coverage in line with the modified PTC eligibility criteria under the ARP, and then take steps and expend resources to end these new procedures since this temporary modification no longer applies after taxable year 2022. As part of this process, HHS would need to ensure the adoption of appropriate procedures, proper approvals, and ongoing oversight. To foreclose the possibility that Federal funding and resources will be diverted from efforts to provide direct benefits to consumers made available under recent legislation to optional programs, HHS proposed to repeal the Exchange DE option. As explained in the proposed rule, this would help ensure that available resources are allocated consistent with administration health care priorities and dedicated to implementation of newly-enacted Federal laws that provide greater financial assistance and protections to consumers.

HHS further explained that repealing the Exchange DE option should generally have a minimal impact on states and other interested parties.

³⁶ 86 FR 7009 (Jan. 25, 2021).

³⁷ 86 FR 7793 (Feb. 2, 2021).

³⁸ Health Insurance Marketplace® is a registered service mark of the U.S. Department of Health & Human Services.

³⁹ 86 FR 7793 (Feb. 2, 2021).

⁴⁰ <https://www.cms.gov/newsroom/press-releases/more-25-million-americans-gain-health-coverage-during-special-enrollment-period>.

⁴¹ <https://www.cms.gov/newsroom/press-releases/more-25-million-americans-gain-health-coverage-during-special-enrollment-period>.

⁴² Public Law 117-2.

⁴³ <https://www.cms.gov/newsroom/press-releases/more-25-million-americans-gain-health-coverage-during-special-enrollment-period>.

⁴⁴ Title I of Division BB of the Consolidated Appropriations Act, 2021, Public Law 116-260 (Dec. 27, 2020).

States with State Exchanges already could engage with DE entities preceding the addition of § 155.221(j). In addition, the FFEs have already implemented the DE program (including classic direct enrollment and enhanced direct enrollment, or EDE), which provides broad availability of non-Exchange websites to assist consumers applying for, or enrolling in QHPs through an FFE or SBE-FP with APTC and CSRs, when otherwise eligible.⁴⁵ Additionally, HHS noted that nothing in the previous regulatory framework prohibited State Exchanges from engaging DE entities similar to the FFEs in order to supplement Exchange operations in their states should they so choose. HHS also noted that although HHS understands that several State Exchanges have engaged with DE entities to discuss possibilities for collaboration, State Exchanges and other stakeholders nearly universally cautioned against the Exchange DE option in public comments submitted in response to the initial proposal to establish the Exchange DE option. HHS further noted that, to date, no state had expressed interest in implementing the Exchange DE option.

Finally, in reviewing § 155.221(j) in line with E.O. 13985 and E.O. 14009, and after further consideration of public comments received when the Exchange DE option was proposed, HHS explained in the proposed rule that HHS determined that the Exchange DE option is inconsistent with policies described in E.O. 13985 and sections 1 and 3 of E.O. 14009. Consistent with many public comments received when the Exchange DE option was proposed, HHS noted that HHS believed that shifting away from *HealthCare.gov* or State Exchange websites as the primary pathway to enroll in and receive information about coverage would harm consumers by unnecessarily fracturing enrollment processes among the Exchange and possibly multiple DE entities operating in a state. HHS noted that such a shift would be particularly harmful now when over 2.5 million consumers have relied upon and successfully navigated *HealthCare.gov* and State Exchange websites during the COVID-19 special enrollment period to enroll in Exchange coverage. HHS also agreed with many commenters who noted that a fractured process could foster consumer confusion about how to get covered and what coverage options are available, since consumers could be directed to DE entities that only offer

assistance with a limited selection of products and some of those products may not provide, for example, MEC for consumers.⁴⁶ Many commenters raised concerns that this consumer confusion or limited product selection through DE entities could also potentially disrupt coordination of coverage with other insurance affordability programs, including Medicaid and CHIP, which is inconsistent with HHS's "no wrong door" policy.⁴⁷ In addition, these consequences could act as an unnecessary barrier to consumers seeking Medicaid or ACA coverage rather than facilitating enrollment in comprehensive coverage, and could have additional downstream impacts including an increased uninsured or underinsured population, or more consumers enrolling in less comprehensive coverage options. These downstream impacts could lead to health inequities by disparately impacting certain vulnerable groups that tend to have a greater need for comprehensive coverage or rely more heavily on Medicaid and CHIP. These concerns and the accompanying risks to the health and well-being of underserved groups and consumers in general are heightened as the COVID-19 PHE continues.

After finding the Exchange DE option inconsistent with recent Executive Orders, to ensure that resources are not diverted from fulfilling requirements under the new health care legislation and other initiatives like the COVID-19 special enrollment period, and because no state had yet expressed interest in implementing the Exchange DE option, HHS proposed to remove § 155.221(j) and repeal the Exchange DE option. As explained in the preamble section regarding user fee rates for the 2022 benefit year (§ 156.50), HHS also proposed to repeal the accompanying user fee rate for FFE-DE and SBE-FP-DE states for 2023.

The following is a summary of the comments received and HHS's responses to the proposed repeal of the Exchange DE option (§ 155.221(j)).

Comment: The overwhelming majority of commenters supported the

proposal to repeal the Exchange DE option. These commenters both endorsed the rationale behind this proposal, and reiterated concerns about the potential negative ramifications of the Exchange DE option that were expressed in comments when the Exchange DE option was originally proposed in the 2022 Payment Notice. These include a lack of empirical research to quantify potential impacts or demonstrate the value that would be added by implementation of this option; the potential for consumer confusion due to fragmentation among multiple DE entities; the potential for DE entities with misaligned incentives to steer consumers toward less comprehensive coverage options or fail to inform consumers that they are eligible for Medicaid or CHIP; an increase in funding and resources that would be needed to provide effective oversight; and other downstream impacts, including the potential for an increase in uninsured and underinsured populations, particularly within the QHP, Medicaid, and CHIP populations.

Several commenters also raised health equity concerns, asserting that the Exchange DE option could have a disproportionate impact on certain underserved or historically-marginalized groups, and others that face barriers navigating the health care system to get coverage. Supporting commenters commented on behalf of those with pre-existing conditions, the LGBTQ+ population, women and children, those with substance use disorders, young adults, and others. One commenter noted that the Exchange DE option would disproportionately impact historically-marginalized populations by making Medicaid less accessible, asserting that DE entities do not necessarily provide Medicaid eligibility information to consumers. Another commenter noted that making Medicaid less accessible would be particularly harmful to women of color and those in the LGBTQ+ community who, due to discrimination and depressed wages, are disproportionately eligible for Medicaid and CHIP. Several commenters expressed concern that the Exchange DE option would disproportionately impact people with substance use disorders and mental health conditions given the increased prevalence of those conditions during the PHE. Commenters expressed concern that those with limited health literacy also could be particularly harmed by the Exchange DE option, citing consumers in underserved communities, young people, people who do not speak English as a first language, and others. These commenters

⁴⁵ The FFE DE pathways are also available in SBE-FP states. See 45 CFR 155.220(l) and 155.221(i).

⁴⁶ Multiple commenters cited the following report as support for their comments related to DE entities offering limited plan selection and potential disruptions to coordination of coverage with other insurance affordability programs: <https://www.cbpp.org/research/health/direct-enrollment-in-marketplace-coverage-lacks-protections-for-consumers-exposes>.

⁴⁷ This policy is intended to ensure that consumers can complete a single eligibility application to receive determinations of eligibility across multiple health insurance affordability programs, including for QHPs, APTC, CSRs, as well as Medicaid and CHIP. See, for example, sections 1311(d)(4)(F) and 1413 of the ACA.

stated that such consumers are particularly susceptible to being harmed by insufficient information, coverage, and hidden costs. One commenter also noted that women generally have more health care needs and are more vulnerable to high health costs, which means enrolling in substandard coverage could result in care being delayed or denied, medical debt, and overall worse health outcomes. Commenters also noted that the potential increase in the number of consumers enrolled in substandard coverage as a result of the Exchange DE option would be particularly harmful for consumers with pre-existing conditions, since through such substandard coverage they could experience a denial of coverage due to their pre-existing conditions. Most of these commenters underscored that health equity concerns are heightened by the ongoing PHE.

Supporting commenters strongly encouraged the repeal to be finalized as proposed to remedy these concerns and protect consumers, particularly underserved and historically-marginalized consumers.

Response: HHS appreciates the support of this proposal and generally agrees with commenters' concerns, particularly those regarding the potential negative impacts to underserved and historically-marginalized consumers during the PHE. The new enrollment and coverage opportunities available to consumers, including the special enrollment period to enroll in Exchange coverage through *HealthCare.gov* or their State Exchange website during the COVID-19 PHE, and the increased financial assistance under the ARP, have proven to be successful at increasing enrollment in comprehensive coverage options, such as ACA coverage offered through Exchanges.⁴⁸ HHS believes it is critical to build on this success by maximizing opportunities for consumers to get comprehensive ACA coverage through the Exchanges and to enroll in insurance affordability programs (for example, Medicaid and CHIP), when eligible. Moreover, HHS believes that this will best serve underserved and historically-marginalized groups, as well as support health equity. For example, as raised in comments that are summarized earlier in this preamble, consumers in these groups tend to have a greater need for more comprehensive coverage (for example, those with pre-existing conditions) or to require robust

consumer support and ample opportunity to successfully navigate the health care system (for example, those with limited health literacy). HHS believes that focusing resources on the Exchanges and the new health care programs they are leading is the best approach to support these, and other consumer needs, for underserved and historically-marginalized groups, and for consumers in general.

HHS also notes that repealing the Exchange DE option will not foreclose states' option to leverage the existing FFE DE pathways,⁴⁹ nor the ability of State Exchanges to implement DE pathways similar to the FFEs, should they find that it is appropriate given their specific market dynamics, priorities, and needs. However, on balance, HHS believes there is much greater risk that the Exchange DE option could serve as a barrier to consumers getting comprehensive coverage rather than facilitate such enrollment. The repeal of the Exchange DE option also permits HHS to direct available resources to implementation of the new Federal requirements (for example, the No Surprises Act consumers protections and the ARP increased subsidies), rather than diverting resources to implement an optional program. Finally, as detailed earlier in this preamble, it aligns with the policy goals and directives in the recent Executive Orders to advance health equity for all, protect and strengthen the ACA, and eliminate unnecessary difficulties to obtaining health insurance. After consideration of comments, HHS is finalizing the repeal of the Exchange DE option and accompanying user fees, as proposed.

Comment: Commenters requested clarification regarding the scope of the proposed repeal and whether HHS's intent is to eliminate the existing FFE DE pathways or just to eliminate the Exchange DE option.

Response: HHS clarifies that the existing FFE DE pathways, including both classic DE and EDE, will not be impacted by the repeal of the Exchange DE option. Those pathways will continue to be available to consumers shopping for Exchange coverage in FFE and SBE-FP states. In addition, states with State Exchanges also still have the option to leverage DE should they choose to do so based on their specific market dynamics, priorities, and needs. The proposed repeal, which HHS is finalizing in this rule, is specific to removing the Exchange DE option codified at § 155.221(j) and the

accompanying FFE-DE and SBE-FP-DE user fees. The other Federal requirements applicable to the FFE DE pathways, as outlined in §§ 155.220, 155.221, and 156.1230, remain intact.

Comment: Several opposing commenters asserted it is premature to repeal the Exchange DE option on the grounds of lacking state interest, given the limited time since the proposal was finalized. They stated that reliance on this ground was questionable in light of the many other health care priorities that have occupied states such as implementing and operationalizing the health care provisions of recent legislation, including the ARP. Some opposing commenters recommended that the rollout of the Exchange DE option merely be delayed, rather than repealed, to give states additional time to explore its feasibility. Several commenters also expressed general support for the Exchange DE option, noting that it meets all applicable ACA statutory and regulatory requirements. One commenter suggested that the lowered user fee for the Exchange DE option for FFE and SBE-FP states could be attractive to states and weigh favorably in the balance for those states who may be interested in pursuing the Exchange DE option, if given more time to consider it. This commenter noted that another attractive feature to states is the potential cost savings on consumer support functions resulting from potentially having more enrollment channels available to consumers. Other commenters in opposition of the proposed repeal stated that there would be no cost to the Federal Government beyond oversight costs in states that elected to implement the Exchange DE option.

Response: HHS acknowledges that the Exchange DE option was only recently finalized and it is plausible that but for competing health care priorities perhaps some states would express interest in the Exchange DE option. However, HHS clarifies that the lack of interest from states was just one factor that led to the proposed repeal of the Exchange DE option. As detailed earlier in this preamble and in the proposed rule, HHS was also concerned that permitting the establishment of the Exchange DE option would detract from efforts to implement new Federal requirements, including consumer protections against surprise medical billing, for which HHS is now responsible and centrally involved in implementing. HHS was also concerned about the additional complexity to Exchange operations resulting from newly passed legislation that could impact the successful implementation of the Exchange DE

⁴⁸ <https://www.cms.gov/newsroom/press-releases/more-25-million-americans-gain-health-coverage-during-special-enrollment-period>.

⁴⁹ The FFE DE pathways are also available in SBE-FP states. See 45 CFR 155.220(l) and 155.221(i).

option, which could negatively impact consumers ability to enroll in comprehensive coverage. Finally, the proposal was made following HHS's evaluation of the Exchange DE option as directed by EOs 13985 and 14009, which determined the option was inconsistent with the policies outlined in those Executive Orders to advance health equity for all, protect and strengthen the ACA, and eliminate unnecessary difficulties to obtaining health insurance.

HHS appreciates that there are potentially attractive features of the Exchange DE option both for states and the Federal Government, particularly from a financial perspective. This was one of the considerations that led to the proposed establishment of the Exchange DE option. However, HHS does not believe that a reduced user fee or potential savings on consumer support costs outweighs the potential harm to consumers, or other considerations, outlined earlier in this preamble and in the proposed rule, that HHS considered as part of its recent evaluation of the Exchange DE option. Delaying the rollout of the Exchange DE option and giving states more time to evaluate its feasibility would not assuage the multitude of concerns expressed by the public or those outlined earlier in this preamble and in the proposed rule, including the need to focus health care resources on the emergent needs of struggling vulnerable and historically-marginalized consumers and the need to focus available Department resources on implementing new Federal requirements, including the new consumer protections against surprise medical billing. In part 1 of the 2022 Payment Notice final rule, HHS outlined many potential direct and indirect costs of startup, approval, and oversight.⁵⁰ HHS therefore disagrees that the Federal Government would incur only oversight costs in states that elect to implement the Exchange DE option.

Comment: All opposing commenters argued that state flexibility, particularly the flexibility to tailor enrollment portals, should not be curtailed, especially during a PHE. Relatedly, these commenters asserted that consumers universally benefit from an increase in choice. One of these commenters stated that DE entities would serve to supplement and extend the reach of Exchanges rather than replacing them.

Response: HHS agrees that proposals that encourage and promote state flexibility are important, as states are best suited to tailor programs to address

local health care priorities and the needs of their residents. HHS also reiterates that the existing FFE DE pathways are not impacted by the repeal of the Exchange DE option. States using the *HealthCare.gov* platform and State Exchanges will still have the option to leverage DE as a supplement to the Exchange should they find that it would provide value for their consumers given their specific market dynamics, priorities, and needs. States that currently use *HealthCare.gov* also have flexibility to transition to a State Exchange model and adapt Exchange functions to their local markets and unique needs of their residents. HHS also believes that in this situation, on balance, the potential for expanded choice does not outweigh the potential consumer harms when there is a danger of fragmenting consumers' path to getting comprehensive coverage and directing consumers to less comprehensive coverage options that, in many cases, will not cover their health care costs. This places an outsized burden on consumers that, after further evaluation, HHS determined is unnecessary given their existing choice of multiple enrollment pathways offered by Exchanges, QHP issuers, web-brokers, agents and brokers, generally harmful for consumers, and unacceptable during a PHE.

HHS also highlights the recent enrollment increases driven by *HealthCare.gov* and State Exchange websites, which are outlined earlier in this preamble. In particular, HHS reiterates that as of August 10, 2021, approximately 2.5 million consumers have enrolled in coverage through *HealthCare.gov* and State Exchange websites during the COVID-19 special enrollment period, and have reduced their monthly premiums by \$40 per person per month due to the ARP's premium credits, with more than one-third of consumers finding coverage for \$10 or less per month.⁵¹ In addition, out-of-pockets costs have fallen for new consumers that have enrolled since April, with the median plan deductible falling by nearly 90 percent from \$450 to \$50. This increased enrollment and cost savings to consumers, which has been driven by the current Exchange programs, further demonstrates their importance and effectiveness.

Comment: All opposing commenters asserted that DE entities and their platforms are better suited than Navigators and centralized, government-run Exchanges to innovate to meet

consumer needs. Relatedly, they argue that the FFE DE pathways have in many ways surpassed the consumer support functionality of *HealthCare.gov*, and that this is largely driven by competition among DE entities to attract consumers. They also claim that the success of the FFE DE pathways is evidenced by the enrollment statistics from the successful plan year 2021 open enrollment period.⁵² One commenter argued that EOs 13985 and 14009 would actually be better served by maintaining the Exchange DE option since it would provide more consumer-centric access to coverage, including for vulnerable populations.

Response: While HHS does not agree with many of these characterizations, HHS reiterates again that the FFE DE pathways will not be impacted by the repeal of § 155.221(j). Those pathways and their success may continue unimpeded since HHS is only repealing the Exchange DE option. DE may indeed be the right choice for some states and certain consumers, and HHS does not intend to diminish its success or inhibit innovation in this area. However, HHS maintains that the policy goals outlined in EOs 13985 and 14009 are best served by repealing the Exchange DE option. More specifically, the dangers that this optional program that would remove the centralized Exchange website could fragment consumers' path to getting comprehensive coverage, direct consumers to less comprehensive coverage options that, in many cases, will not cover their health care costs, and disproportionately impact certain underserved and historically marginalized groups are inconsistent with advancing health equity, protecting and strengthening the ACA, and eliminating unnecessary barriers to obtaining health insurance. These dangers are heightened during a PHE. HHS believes that access to comprehensive coverage options, including Exchange plans, and advancing health equity among consumers will be best served by enhancing access to coverage through proven enrollment channels like the Exchanges or the FFEs' DE pathways, and eliminating optional programs that have the potential to cause significant consumer confusion and harm at a time when consumer protection and enrollment in comprehensive coverage

⁵¹ <https://www.cms.gov/newsroom/press-releases/more-25-million-americans-gain-health-coverage-during-special-enrollment-period>.

⁵² Several commenters cited in particular that CMS data show that the FFE DE pathways more than doubled enrollments during the plan year 2021 open enrollment period, increasing from 521,000 to 1,130,000. They also noted that the FFE DE pathways have attracted a higher proportion of new consumers and increased the number of consumers who made active plan selections.

⁵⁰ See 86 FR 6169–6170.

is of paramount importance. Notwithstanding the claim that centralized, government-run Exchanges are not as well equipped to innovate to meet consumer needs as DE entities and platforms, HHS highlights that Exchanges do innovate, and are central participants in innovative programs. For instance, the State Exchanges and *HealthCare.gov* have administered innovative new health care programs in 2021 detailed previously⁵³ that have resulted in 2.5 million consumers successfully enrolling through the Exchanges with significant premium assistance. In addition, the FFEs have been central participants in innovating through the Federal DE pathways.⁵⁴ These pathways are designed to foster innovation of new consumer-based tools and functionality by approved DE partners.⁵⁵ HHS believes that these and other examples of Exchange innovation and collaboration with the private sector help dispel concerns about the ability of centralized, government-run Exchanges to meet consumer needs.

Comment: Opposing commenters argued that concerns about consumers being steered toward non-comprehensive coverage options like short-term limited duration insurance or association health plans are exaggerated since there are existing FFE DE requirements and limitations that would mitigate such concerns. They also highlighted that § 155.221(j) requires that a State Exchange electing to implement the Exchange DE option must have at least one DE entity that meets all requirements of the FFE DE program, including displaying all available QHPs. These commenters also suggested that concerns about potential disruptions to coordination of coverage with insurance affordability programs like Medicaid and CHIP are exaggerated because the DE entities participating in the FFE DE pathways use the same single, streamlined application and eligibility notices as *HealthCare.gov* to assist the Exchange with rendering an eligibility determination for all insurance affordability programs in compliance with the “no wrong door” policy.

Response: HHS appreciates that there are Federal DE requirements and operational practices in place designed to protect consumers, including certain requirements to protect against steering QHP consumers to less comprehensive coverage options.⁵⁶ The Exchange DE option also included certain safeguards, including the requirement that at least one DE entity must meet all of the requirements to participate in the FFE DE program. However, HHS maintains that the previously identified dangers that this optional program could harm consumers by fragmenting the path to comprehensive coverage, directing consumers to less comprehensive coverage options, and disproportionately impacting certain underserved and historically marginalized groups are inconsistent with advancing health equity, protecting and strengthening the ACA, and eliminating unnecessary barriers to obtaining health insurance. These dangers are real,⁵⁷ they are heightened during a PHE, and after further evaluation, HHS determined they place an unnecessary and unacceptable outsized burden on consumers. HHS believes that access to comprehensive coverage options, including Exchange plans, and advancing health equity among consumers will be best served by enhancing access to coverage through proven enrollment channels, which includes maintaining a centralized Exchange website for consumers to apply for an enroll in QHPs and insurance affordability programs. The increased enrollment through Exchange websites during the COVID-19 special enrollment period underscores the importance of maintaining these known enrollment pathways for consumers. Finalizing the repeal of the Exchange DE option also ensures HHS can focus resources and efforts on implementing new Federal requirements, including consumer protections against surprise medical billing, for which HHS is now responsible and centrally involved in implementing, rather than on implementing and overseeing an optional program, which has the potential to cause significant confusion and harm at a time when consumer protection is paramount. Finally, HHS reiterates that the repeal of the Exchange DE option does not impact or change the other Federal requirements applicable to the FFE DE pathways, which will

continue to be available in FFE and SBE-FP states. States with State Exchanges can also still leverage DE as a supplement to the Exchange website should they find it would provide value for their consumers given their specific market dynamics, priorities, and needs.

After consideration of these comments, HHS is finalizing the repeal of the Exchange DE option and the FFE-DE and SBE-FP-DE user fees, as proposed.

4. Annual Open Enrollment Period Extension (§ 155.410(e))

HHS proposed to amend paragraph (e) of § 155.410, which provides the dates for the annual individual market Exchange open enrollment period in which qualified individuals and enrollees may apply for or change coverage in a QHP. The annual individual market Exchange open enrollment period is extended by cross-reference to non-grandfathered plans in the individual market, both inside and outside of an Exchange, under guaranteed availability regulations at § 147.104(b)(1)(ii). HHS specifically proposed to alter the annual open enrollment period for the 2022 coverage year and beyond so that it begins on November 1 and runs through January 15 of the applicable benefit year.

In previous rulemaking, HHS established that the annual open enrollment period for benefit years beginning on or after January 1, 2018 would begin on November 1 and extend through December 15. In doing so, HHS indicated a preference for a shorter 6-week annual open enrollment period, noting HHS's belief that it provides sufficient time for consumers to enroll in or change QHPs and that an end date of December 15 carries the benefit of ensuring consumers receive a full year of coverage and simplifies operational processes for issuers and the Exchanges.⁵⁸ Accordingly, the annual open enrollment period dates have been set to November 1 through December 15 for the 2018, 2019, 2020, and 2021 plan years. As discussed in the proposed rule, HHS has observed several benefits using the present annual open enrollment period dates. Prior enrollment data suggests that the majority of new consumers to the Exchange select plans prior to December 15 so as to have coverage beginning January 1.

HHS also observed that consumer casework volumes related to coverage start dates and inadvertent dual enrollment decreased in the years after the December 15 end date was adopted,

⁵³ These include the efforts to administer the health care provisions of the ARP and the related COVID-19 special enrollment period.

⁵⁴ One of the critical consumer-centric innovations of the Federal EDE pathway is to enable consumers to access eligibility and enrollment information directly through a DE entity's website by means of various application program interfaces rather than having to re-direct to *HealthCare.gov*.

⁵⁵ For instance, DE entities may offer plan comparison tools with functionality targeted specifically to serve the needs of their consumer base.

⁵⁶ See, for example, 45 CFR 155.220(c)(3)(i)(A)—(L), 155.220(j), 155.221(b)(1)-(3) and 156.1230(a) and (b).

⁵⁷ See, e.g., <https://www.cbpp.org/research/health/direct-enrollment-in-marketplace-coverage-lacks-protections-for-consumers-exposes>.

⁵⁸ See 82 FR 18346 at 18381.

suggesting that the consumer experience was improved by having a singular deadline of December 15 to enroll in coverage for the upcoming plan year. HHS noted that an extension to January 15 may cause some previously observed consumer confusion to resurface surrounding the need to enroll by December 15 for a full year of coverage versus the final deadline of January 15 to enroll for a plan that would begin on February 1. This confusion could cause some consumers to miss out on coverage for the month of January altogether. A January 15 end date may also require enrollment assisters allocate budget resources over a longer period of time.

However, after observing the effects of a 6-week annual open enrollment period over these years, HHS has also observed negative impacts to consumers that may justify an extension of the annual open enrollment period end date to January 15. In particular, HHS has observed that consumers who receive financial assistance, who do not actively update their applications during the annual open enrollment period, and who are automatically re-enrolled into a plan are subject to unexpected plan cost increases if they live in areas where the second lowest-cost silver plan has dropped in price. These consumers will experience a reduction in their allocation of APTC based on the second lowest-cost silver plan price, but are often unaware of their increased plan liabilities until they receive a bill from the issuer in early January after the annual open enrollment period has concluded. Extending the annual open enrollment period end date to January 15 would allow these consumers the opportunity to change plans after receiving updated plan cost information from their issuer and to select a new plan that is more affordable to them. HHS also noted in the proposed rule that HHS has also observed concerns from Navigators, CACs, and agents and brokers that the current annual open enrollment period does not leave enough time for them to fully assist all interested Exchange applicants with their plan choices. Extending the annual open enrollment period end date to January 15 would allow more time for consumers to seek assistance from one of these entities. Together, the impacts of providing consumers with more time to react to updated plan cost information and more time to seek enrollment assistance may improve access to health coverage. The additional time for enrollment assistance provided by this proposal may be particularly beneficial to consumers in underserved communities

who may face time or language barriers in accessing health coverage by extending the period in which these consumers can seek in-person assistance to enroll.

HHS sought comment on whether a January 15 end date would provide a balanced approach to providing consumers with additional time to make informed plan choices and increasing access to health coverage, while mitigating risks of adverse selection, consumer confusion, and issuer and Exchange operational burden. HHS invited comments from stakeholders that would experience specific benefits or adverse effects from a January 15 end date, and encourage comments on potential impacts to resources, consumer assistance budgets, overall enrollment numbers, premiums, and market stability. HHS sought comment on whether this extension would incentivize consumers who need coverage to begin on January 1 to still make a choice and enroll by December 15, while also preserving sufficient time in the remainder of the plan year for issuers and Exchanges to perform other obligations such as QHP certification.

HHS further invited comments on alternative approaches to extending the annual open enrollment period to address coverage gaps or enrollment challenges facing consumers and stakeholders. HHS also invited comments to address whether HHS should explore the possibility of a new special enrollment period, such as for current enrollees who are automatically re-enrolled and experienced a significant cost increase, to address concerns for specific consumer challenges as an alternative to extending the annual open enrollment period. HHS also noted that HHS is considering whether approaches such as enhanced noticing or special, targeted outreach would address the needs of consumers who are automatically re-enrolled in areas where the second lowest-cost silver plan drops in value, thereby reducing APTC amounts. HHS sought comment on how HHS may improve communications and consumer engagement around potential cost changes for consumers who do not actively re-enroll in coverage. HHS also noted that HHS is considering if improved education and outreach during the coverage year to raise awareness of existing special enrollment period opportunities, such as those for loss of coverage or becoming newly eligible or ineligible for financial assistance, may serve consumers who do not enroll or change plans during the annual open enrollment period. HHS sought comment on whether adoption of

these or other outreach approaches would be a viable alternate approach to finalizing its proposal to extend the annual open enrollment period end date to January 15.

HHS noted that HHS anticipated that if an annual open enrollment period end date of January 15 were finalized, this change would apply to all Exchanges, including State Exchanges for the 2022 coverage year and beyond. HHS noted that in preceding plan years, a majority of State Exchanges operating their own eligibility and enrollment platform have used special enrollment period authority to offer additional enrollment time beyond the end date of December 15 in the Exchanges on the Federal platform. HHS invited additional comments on State Exchange flexibility, as well as operational challenges relating to State Exchange implementation of the proposed change for 2022 and beyond.

HHS is finalizing this policy for the FFEs and SBE-FPs, and HHS codifies flexibility for State Exchanges that operate their own eligibility and enrollment platform to set individual market annual open enrollment period end dates no earlier than December 15 and to offer accelerated effective date rules. HHS is clarifying that the annual open enrollment period end dates chosen by State Exchanges operating their own eligibility and enrollment platform will apply to all non-grandfathered plans in the individual market, both inside and outside of an Exchange, under guaranteed availability regulations at § 147.104(b)(1)(ii). The following is a summary of the comments received and HHS's responses to its proposals related to the annual open enrollment period extension (§ 155.410(e)).

Comment: The majority of commenters supported HHS's proposal. Commenters agreed that lengthening the annual open enrollment period would provide valuable time to consumers to seek in-person assistance and make informed plan choices. Many commenters agreed that this time would be particularly helpful to those who are auto-reenrolled into coverage, but receive a lower subsidy than the prior year because the cost of their benchmark plan has dropped. Commenters also noted additional groups that would benefit from this extension: Consumers whose coverage is terminated towards the end of the calendar year and who do not become aware of its termination until after January 1, consumers whose Medicaid eligibility is ending as the result of the potential expiration of the continuous enrollment provisions in section 6008(b)(3) of the Families First

Coronavirus Response Act (Pub. L. 116–127), and consumers whose share of premiums may increase in plan year 2022 due to the expiration of extra subsidies provided for under the ARP. A January 15 end date would provide these consumers extra time and a streamlined process to understand their eligibility and plan cost changes and enroll in new coverage.

Several commenters highlighted the complex medical needs of consumers with chronic and serious medical conditions, noting that a longer annual open enrollment period would give these consumers more time to review and compare plan options, provider networks, and prescription drug offerings. Organizations and individuals providing application and enrollment assistance commented that there is often not enough time to provide individual or in-person help to all consumers who request it at the end of the current 6-week annual open enrollment period. Other commenters agreed with HHS's proposal that a longer annual open enrollment period would allow underserved populations more time to seek in person assistance and reduce barriers to enrollment, and that the proposal would allow agents and brokers, Navigators, and other consumer assisters more time to help and serve consumers shopping for plans. Finally, many commenters noted that the months of November and December are some of the busiest for consumers, and that holidays and end of the year activities cause significant time and financial constraints that are barriers to enrollment. Commenters argued that many consumers would benefit from additional time in January to complete plan shopping and enrollment activities.

Response: HHS agrees with these comments and is finalizing the policy to extend the annual open enrollment period to January 15 of the applicable benefit year, as proposed, and HHS codifies flexibility for State Exchanges that operate their own eligibility and enrollment platform to set individual market annual open enrollment period end dates no earlier than December 15 and to use accelerated effective date rules.

Comment: Many commenters noted that the majority of State Exchanges have already extended their annual open enrollment periods beyond the current December 15 deadline used by Exchanges on the Federal platform, and that State Exchanges have achieved enrollment gains in the month of January without introducing adverse selection into the market. Some State Exchange commenters noted that a longer annual open enrollment period

allowed new consumers to enroll and resulted in a healthier risk pool mix. Another commenter noted that while most consumers continued to choose plans in December in order to have coverage effective January 1, the additional time in January offered flexibility for consumers who needed more time to weigh coverage options and enroll.

Many state commenters noted that State Exchanges that offered extended periods for the annual open enrollment period beyond the end date used by the Exchanges on the Federal platform in some cases offered more accelerated effective date rules during the annual open enrollment period such that plan selections made by the last day of the month are effective the first day of the following month. These commenters asked that this flexibility be maintained and that January 15 be the minimum end date for the annual open enrollment period in the State Exchanges. Other commenters noted that not all State Exchanges have chosen to extend their annual open enrollment periods into January and requested that State Exchanges maintain an ability to end the annual open enrollment period earlier than January 15. These commenters noted that State Exchanges may face operational burdens in adjusting their systems to accommodate the January 15 end date and that State Exchanges should maintain autonomy to set annual open enrollment period dates that best serve their populations.

Response: HHS appreciates the comments highlighting evidence from State Exchange experiences with longer effective annual open enrollment periods, and are finalizing the policy to extend the annual open enrollment period to January 15. HHS agrees with commenters that State Exchanges are best suited to address the needs of their markets and are therefore codifying flexibilities for State Exchanges that operate their own eligibility and enrollment platform to set annual open enrollment period end dates no earlier than December 15. HHS also is codifying that these State Exchanges may extend their annual open enrollment periods beyond the end date of January 15 that will be used by the Exchanges on the Federal platform and may adopt more flexible accelerated effective date rules.

Comment: Many commenters encouraged HHS to extend the annual open enrollment period even further, specifically to January 31. Commenters also asked that HHS use accelerated effective dates to make coverage available February 1 for plan selections received by January 31. Other

commenters asked us to consider beginning the annual open enrollment period earlier in the year, for example on October 15, while still maintaining an end date of December 15 or December 31, as an alternative way to extend the total length of the annual open enrollment period. Still other commenters asked HHS to explore an October 15 start date in addition to the proposed extension, noting that the date would align with the beginning of Medicare's annual open enrollment period and that this alignment would facilitate additional consumer outreach and enrollments. Another commenter suggested providing an annual open enrollment period of January 1 through March 31 to avoid the holiday season and end of the calendar year altogether.

Response: HHS recognizes that a January 31 end date would provide additional time for consumers to enroll, and that some State Exchanges have adopted this date. However, HHS believes the proposed date of January 15 sufficiently balances its priorities of allowing consumers additional time to enroll after the end of the calendar year, while still promoting full coverage year enrollment and minimizing administrative burdens on Exchanges and issuers associated with longer annual open enrollment periods. Given the high volume of transactions processed by the Federal platform, HHS's operational experience suggests that adopting accelerated effective dates for the annual open enrollment period could cause delays in enrollments and claims processing and would require further study. Accordingly, HHS is not considering requiring changes to effective date rules at this time, but as noted earlier, is codifying flexibility for State Exchanges operating their own eligibility and enrollment platforms to adopt accelerated effective dates.

While beginning the annual open enrollment period in October instead of November 1 would effectively lengthen the total annual open enrollment period timeframe, it would not address the needs of consumers who receive updated plan cost information or who experience program eligibility changes after January 1 and would also create administrative burdens on Exchanges and issuers to complete QHP plan certification and other pre-enrollment readiness activities. Similarly, HHS believes a change to begin the annual open enrollment period on January 1 and end in March would require a shift of the plan year calendar and create significant administrative burden on Exchanges, issuers, and state regulators, and HHS is not considering such a change at this time.

Comment: Other commenters opposed the proposal to extend the annual open enrollment period to January 15. Commenters stated that this change would introduce adverse selection into the market, as more consumers would delay enrollment and may enroll in January only after needing care. Others noted that the change would increase administrative burdens and marketing and operational costs on issuers. Commenters noted that consumers have become accustomed to a 6-week annual open enrollment period and some commenters assisting consumers with enrollment activities noted that in their experience consumers did not need more time. Other commenters argued that the change would actually decrease total enrollment figures, as measured by total coverage months, as more consumers delay enrollment and neglect coverage for the month of January.

Response: HHS acknowledges commenters' concerns regarding consumer confusion and coverage gaps, and recognizes that HHS will need to engage in consumer outreach activities to ensure consumers are aware of the new deadlines and the implications of signing up by December 15 for a January 1 effective date. However, HHS notes that the experience from State Exchanges operating their own eligibility and enrollment platforms suggests that extending the annual open enrollment period into January does result in increased consumer enrollments and does not introduce adverse selection into market. State Exchange commenters noted that the majority of consumers still enrolled in time to effectuate coverage for January 1, but that the Exchanges were able to achieve additional enrollments in January from consumers who simply missed the deadline or needed more time and help enrolling. The experience from these State Exchange commenters is also consistent with other comments received in support of this proposal which noted that underserved consumers, consumers with complex health needs, and consumers with unexpected plan cost or eligibility changes at the end of the year do not have enough time to shop and get in-person assistance under the current annual open enrollment period timeframe.

Comment: HHS received comments in support of its suggestion to offer a special enrollment period for current enrollees who are automatically re-enrolled and experienced a significant cost increase as an alternative to extending the annual open enrollment period, and a request that HHS delay offering this special enrollment period

until 2023. Other commenters opposed the idea of a targeted special enrollment period and noted that special enrollment periods create complexity and costs for issuers and are difficult and burdensome for consumers to navigate. Commenters stated that an extended annual open enrollment period offers a much more streamlined approach to achieving the policy goal of allowing consumers to change plans in response to updated cost information as compared to a special enrollment period. Commenters also supported HHS's suggestions to improve consumer outreach and education activities to address enrollment barriers, but did not agree this outreach is an adequate substitute for extending the annual open enrollment period.

Response: While HHS is not aware of increased issuer costs or consumer burden in the State Exchanges that have used special enrollment periods to effectively lengthen the annual open enrollment period, HHS acknowledges that the targeted special enrollment period as discussed in this rule would be limited to certain consumers meeting specified criteria and, as such, could require additional administrative steps for issuers, consumers, and Exchanges. HHS agrees that an extended annual open enrollment period offers a more streamlined approach for consumers, and also serves the added benefit of allowing other consumers, such as those with complex health needs, those in underserved communities, and those who receive a lower subsidy than the prior year that they are not aware of until receiving their January bill more time to determine their best coverage option.

Comment: Other commenters suggested HHS could do more to improve renewal notices to address the challenges faced by consumers who were automatically re-enrolled but then experienced a significant cost increase as an alternative to extending the annual open enrollment period. Commenters suggested HHS consider aligning operational timelines and allowing issuers to provide more timely and accurate premium tax credit and plan cost information to consumers. Commenters suggested HHS could improve its communications around the automatic re-enrollment process to better avoid consumers receiving surprising plan cost information after the benefit year has begun. Another commenter asked HHS to consider a policy for providing retroactive terminations to consumers who were automatically re-enrolled into coverage that they no longer want, and that such a policy could reduce spending on

APTC paid for these months of inadvertent coverage.

Response: HHS agrees that more improvements can be made in this area, and welcomes the suggestions by commenters to improve renewal notice processes to provide more accurate plan cost information to consumers earlier in the annual open enrollment period. However, after review of the range of public comments received, HHS does not believe improvements to the renewal noticing and automatic re-enrollment process alone is a sufficient alternative to providing additional enrollment time. HHS notes that current HHS policy does allow for consumers to request retroactive terminations under certain circumstance after their coverage has been automatically renewed, and that an extended annual open enrollment period deadline of January 15 will also allow consumers more time to become aware of their enrollment options after automatic reenrollment has occurred.

5. Monthly Special Enrollment Period for APTC-Eligible Qualified Individuals With a Household Income No Greater Than 150 Percent of the Federal Poverty Level Whose Applicable Taxpayer Has an Applicable Percentage of Zero (§ 155.420(d)(16))

In order to make affordable coverage available to more consumers, HHS proposed to codify a monthly special enrollment period for qualified individuals or enrollees, or the dependents of a qualified individual or enrollee, who are eligible for APTC, and whose household income is expected to be no greater than 150 percent of the FPL.⁵⁹ As discussed in the proposed rule, HHS proposed making this special enrollment period available to individuals based on household income level because enhanced financial

⁵⁹ As noted in the proposed rule, a qualifying individual is generally not eligible for a PTC if their household income is below 100 percent of the FPL, but there are a small number of consumers with a household income below 100 percent of the FPL who may qualify for APTC. Specifically, section 36B(c)(1)(B) of the Code provides that a taxpayer with a household income which is not greater than 100 percent of the FPL, and who is a lawfully present immigrant and ineligible for Medicaid due to their immigration status, may qualify for a PTC. Consumers for whom this is the case would be able to qualify for the proposed special enrollment period, as well. Additionally, HHS notes that because individuals would qualify for this special enrollment period based on their household income level, household members who apply for coverage with financial assistance together generally will all qualify for the special enrollment period. However, it is also possible that one household member could trigger the special enrollment period based on a change in their eligibility for APTC—for example, a household member who loses access to an offer of coverage through an employer that is considered affordable based on 26 CFR 1.36B-2(c)(3)(v).

assistance provided by the ARP for tax years 2021 and 2022 is such that many individuals with a household income no greater than 150 percent of the FPL have access to a silver plan with a zero dollar monthly premium after the application of APTC.⁶⁰ Specifically, section 9661 of the ARP amended section 36B(b)(3)(A) of the Code to decrease the applicable percentages used to calculate the amount of household income a taxpayer is required to contribute to their second lowest cost silver plan for tax years 2021 and 2022.⁶¹ The applicable percentages are used in combination with factors including annual household income and the cost of the benchmark plan to determine the PTC amount for which a taxpayer can qualify to help pay for a QHP on an Exchange for themselves and their dependents.⁶² These decreased percentages generally result in increased PTC for PTC-eligible taxpayers, and for those with household incomes no greater than 150 percent of the FPL, the new applicable percentage is zero. As a result of these changes, many low-income consumers with a household income no greater than 150 percent of the FPL whose QHP coverage can be fully paid for with APTC have one or more options to enroll in a silver-level plan without needing to pay a premium after the application of APTC. All of these consumers, if eligible to enroll through an Exchange and to receive APTC, will qualify for CSRs to enroll in a silver plan with an AV of 94 percent.⁶³

HHS proposed that this special enrollment period be available at the option of the Exchange, in order to allow State Exchanges to decide whether to implement it based on their specific market dynamics, needs, and priorities. Additionally, HHS proposed that Exchanges on the Federal platform will implement this special enrollment period by providing qualified individuals who are eligible with a pathway to access it through the *HealthCare.gov* application. HHS proposed that implementation in Exchanges on the Federal platform be consistent with current special enrollment period policy and operations, in particular such that there is no limitation on how often individuals who are eligible for this special enrollment period can obtain or utilize it.⁶⁴ Consistency in this area will

mitigate consumer and other stakeholder confusion and simplify Exchange operations. To provide Exchanges with flexibility to prioritize ensuring that qualifying individuals are able to obtain coverage through this special enrollment period quickly following plan selection, or to implement this special enrollment period in keeping with their current operations, HHS proposed to add a new paragraph at § 155.420(b)(2)(vii) to provide that the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the month following plan selection, at the option of the Exchange.

HHS also proposed to add a new paragraph at § 155.420(a)(4)(ii)(D) to provide that an Exchange must permit eligible enrollees and their dependents to change to a silver-level plan, and to amend paragraph § 155.420(a)(4)(iii), which provides other plan category limitations for other special enrollment periods, to provide that these other plan category limitations do not apply to enrollees or dependents who qualify for the proposed special enrollment period.⁶⁵ Finally, HHS proposed to add a new paragraph at § 147.104(b)(2)(i)(G) to specify that issuers are not required to provide this special enrollment period in the individual market with respect to coverage offered outside of an Exchange, because eligibility for the special enrollment period is based on eligibility for APTC, and APTC cannot be applied to coverage that is not a QHP offered through an Exchange.⁶⁶

In consideration of public comments that HHS received, HHS is finalizing this monthly special enrollment period for APTC eligible consumers with a projected annual household income no greater than 150 percent of the FPL with coverage effective dates and other eligibility parameters as proposed, but is finalizing it so that the special enrollment period is only available during periods of time during which PTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero. HHS is also finalizing a revision to the language of proposed paragraph

§ 155.420(a)(4)(ii)(D) to reflect that an enrollee who is adding a qualified individual or dependent through this special enrollment period may add the newly-enrolling household member to their current QHP; or, change to a silver-level QHP and add the newly-enrolling household member to this silver-level QHP; or, change to a silver-level QHP and enroll the newly-enrolling qualified individual or dependent in a separate QHP. In consideration of concerns raised by commenters as further discussed below, HHS believes that this modification is appropriate to provide clarity on options and limitations for enrollees whose household members newly enroll through this special enrollment period. In particular, this change makes clear that while newly-enrolling qualified individuals and dependents are not subject to plan category limitations, enrollees with a newly-enrolling dependent or other household member may not use the new monthly special enrollment period to change to a plan of a different metal level other than a silver-level QHP to enroll together with their newly-enrolling household member, but can stay in the same plan or change to a silver plan to enroll together with the newly-enrolling household member. This limitation will help to mitigate adverse selection. Also, the revision HHS is finalizing makes clear that the limitation that applies to this new special enrollment period functions similarly to other plan category limitations, such as those at § 155.420(a)(4)(iii)(B) and (C) for enrollees who are adding one or more newly-enrolling dependents or household members to their Exchange coverage.

In addition to finalizing the previously stated modifications, HHS is also finalizing conforming updates to regulatory text at § 155.420(a)(4)(ii)(C). HHS proposed to add new paragraph (a)(4)(ii)(D) which provided that where an enrollee "or" his or her dependents qualify for a special enrollment period under § 155.420(d)(16) and is not enrolled in a silver-level QHP, the Exchange must allow the enrollee and their dependents to change to a silver-level QHP if they elect to change their QHP enrollment. HHS also proposed to align existing regulatory text at § 155.420(a)(4)(ii)(C) with this new paragraph, and with the related special enrollment period triggering event at § 155.420(d)(6)(i) and (ii), by updating a sentence reading "if an enrollee and his or her dependents" to "if an enrollee or his or her dependents." These edits align with corresponding special

⁶⁰ 86 FR 35169.

⁶¹ Public Law 117–2.

⁶² See 26 CFR 1.36B–3(g) for more information on the applicable percentage and its relationship to the PTC.

⁶³ See §§ 155.305(g)(2) and 156.420(a).

⁶⁴ For example, those who qualify for the special enrollment period per § 155.420(d)(8) for qualifying individuals who gain or maintain status as an

Indian, as defined by section 4 of the Indian Health Care Improvement Act, may change their plan selection multiple times each month, noting that only the last plan selection before the applicable cutoff date for coverage each month will take effect for the month in question.

⁶⁵ This provision would not prevent enrollees who qualify for the new special enrollment period from changing to a plan of any category through a special enrollment period that provides this flexibility, including the special enrollment periods at § 155.420(d)(4), (8), (9), (10), (12), and (14).

⁶⁶ See IRC 36B(b)(2)(A), (c)(2)(A)(i).

enrollment period triggering events at § 155.420(d) to which plan category limitations at (a)(4) refer.

As discussed in previous rulemaking, certain provisions under § 155.420(d) defining special enrollment period triggering events refer both to a qualified individual and the qualified individual's dependents, and use "or" (rather than "and") to be clear that when a qualified individual or enrollee, or his or her dependent, experiences the special enrollment period triggering event, all members of a household generally may enroll in or change plans together in response to the event experienced by one member of the household, subject to the limitations in § 155.420(a)(4).⁶⁷ Therefore, HHS is finalizing as proposed this change to § 155.420(a)(4)(ii)(C).

Although HHS proposed revisions to § 155.420(a)(4)(ii)(C) to align with the text of triggering event provisions under § 155.420(d), HHS neglected to propose similar but necessary changes to the text of § 155.420(a)(4)(ii)(A) and (B). HHS intends to propose these changes in future rulemaking. Because this is a technical change, HHS does not anticipate that it will impact Exchanges' operations or messaging. However, if the change does affect an Exchange's operations, CMS will not consider the Exchange to be out of compliance with the rule due to interpreting the plan category limitations rules as aligning with the related special enrollment period qualifying events at § 155.420(d).

This new monthly special enrollment period will be available at the option of the Exchange, as proposed, in order to allow State Exchanges to decide whether to implement it based on their specific market dynamics, needs, and priorities. HHS is also finalizing that Exchanges on the Federal platform will implement this special enrollment period by providing qualified individuals who are eligible with a pathway to access it through the *HealthCare.gov* application.

The APTC benefit changes under the ARP make affordable coverage available to more uninsured people. However, as discussed in the proposed rule, if past trends continue, HHS believes that some consumers who qualify for these benefits under the ARP may continue to forgo enrollment in premium-free coverage due to a lack of awareness of the opportunity to enroll or a misconception about what the coverage would cost, and that low-income

consumers who have lacked coverage for more than a year may be especially difficult to reach.⁶⁸ Therefore, while HHS will undertake extensive outreach and engagement efforts to promote enrollment during the open enrollment period for 2022 coverage and to help ensure consumer awareness of existing special enrollment periods for which they may qualify, given the established challenges with promoting awareness of access to coverage among low-income consumers, HHS believes additional enrollment opportunities for low-income consumers are appropriate and in the best interest of low-income consumers. Additionally, as noted in the proposed rule, the monthly special enrollment period policy would align with E.O. 14009, which requires Federal agencies to identify and appropriately address policies that create barriers to accessing ACA coverage, including access through mid-year enrollment.

In addition to providing certain low-income individuals with additional opportunities to newly enroll in free or low-cost coverage that is available to them, HHS believes this special enrollment period may help consumers who lose Medicaid coverage to regain health care coverage. While, as discussed in the proposed rule, these consumers can already qualify for a special enrollment period due to their loss of Medicaid coverage per § 155.420(d)(1), and may also have access to other flexibilities, whether members of this group of consumers are able to benefit from existing enrollment periods and flexibilities may vary, and may require Exchanges to assess eligibility on a case-by-case basis. This may also require consumers who generally have low household income and who therefore may face other barriers to accessing health care coverage, such as low health insurance literacy levels and lack of internet access, to be aware of the potential for an extended enrollment timeframe and to request it from their Exchange. As also discussed in the proposed rule, after the COVID-19 PHE comes to an end, HHS expects to see a higher than usual volume of low-income individuals transitioning from Medicaid coverage to the Exchanges for at least several months as states begin to catch up on a backlog of redeterminations and terminations for Medicaid beneficiaries after having generally suspended Medicaid disenrollments since March 2020 to comply with the continuous

enrollment provisions in section 6008(b)(3) of the Families First Coronavirus Response Act.⁶⁹ Therefore, while this special enrollment period would not be limited to qualified individuals who have lost Medicaid coverage, HHS noted that providing access to a monthly enrollment opportunity could help some consumers who lose Medicaid coverage to regain health insurance coverage, especially those who do not initially realize that loss of Medicaid is a special enrollment period triggering event. This special enrollment period could help mitigate the risk of long-term coverage disruptions due to the potentially high volume of Medicaid terminations following the end of the COVID-19 PHE, by giving qualifying individuals who lose Medicaid and who may miss or misunderstand notifications about their coverage loss more time to enroll in Exchange coverage.⁷⁰

As proposed, Exchanges that elect to provide this special enrollment period would have the option to require consumers to submit documentation to confirm their eligibility in accordance with their pre- or post-enrollment verification programs. However as discussed in the proposed rule, CMS will determine eligibility for this special enrollment period in Exchanges on the Federal platform based on consumers' attested household income. Once an Exchange on the Federal platform grants this special enrollment period to a consumer based on their attested household income, the Exchange will then verify applicants' projected annual household income consistent with 45 CFR 155.320(c).⁷¹ Specifically, CMS will continue to require consumers whose projected annual household income cannot be verified using a trusted electronic data source to submit documentation to confirm their annual income (currently approved under OMB control number 0938-1207/Expiration date February 29, 2024). CMS will not require submission of household income documentation prior to enrollment, and will not pend the enrollment as part of a pre-enrollment verification process, in part because CMS's experience administering the verification processes for Exchanges on the Federal platform in accordance with § 155.320(c) shows that submitting documentation quickly to verify income can be especially onerous for those at

⁶⁷ See 78 FR 42262. Also, the 2017 Market Stabilization Rule used the phrase "if an enrollee or his or her dependent" when describing the rule that would be finalized at what is now paragraph § 155.420(a)(4)(ii)(A). See 82 FR 18359.

⁶⁸ Key Facts about the Uninsured Population: Kaiser Family Foundation; Nov. 6, 2020, <https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/>.

⁶⁹ Public Law 116-127. These provisions enabled states to receive the temporary Federal Medical Assistance Percentage increase under that section.

⁷⁰ See 86 FR 35170 for discussion of this issue in the proposed rule.

⁷¹ Section 1411(c)(3) of the ACA.

the lowest income levels who may not have ready access to a computer or smartphone, the internet, a copier or scanner, or funds for postage.

In addition to outreach and education efforts, HHS noted that HHS believed that applying plan category limitations to this special enrollment period would help to mitigate adverse selection because it would limit the ability of enrollees to change to a higher metal level plan based on a new health care need and then change back to a silver plan once the health issue is resolved. However, HHS acknowledged that enrollees may still choose to enroll in a silver-level plan that is more expensive than their zero dollar option, and, while HHS believes that enrollees will likely be deterred from changing plans mid-year because such a change will generally mean they lose progress they have made toward meeting their deductible and other accumulators, HHS acknowledged that through a monthly special enrollment period, enrollees could change plans mid-year based on differences in provider networks or prescription drug formularies. HHS sought comment on this proposal and on whether, alternatively, plan category limitations should not be applied. For example, HHS sought comment on whether to instead exempt the proposed special enrollment period at § 155.420(d)(16) from plan category limitations in order to alleviate the implementation burden on Exchanges, or due to a lack of concern that eligible enrollees would use the proposed special enrollment period to change to a plan category other than silver.

HHS also sought comment on the degree to which the risk of adverse selection increases due to the fact that not all qualifying individuals who have a household income no greater than 150 percent of the FPL and whose applicable percentage is therefore set at zero will have access to a silver plan with a zero-dollar premium, and therefore might be more inclined to enroll in coverage due to a health care need and end coverage once this need has been met rather than pay even a relatively small premium.

HHS estimated that this adverse selection risk may result in issuers increasing premiums by approximately 0.5 to 2 percent, and a corresponding increase in APTC outlays and decrease in income tax revenues of approximately \$250 million to \$1 billion, when the enhanced APTC provisions of the ARP are in effect (currently, plan year 2022). HHS described this impact in more detail in the regulatory impact analysis (RIA)

section in the proposed rule.⁷² HHS also discussed some of the reasons adverse selection can be mitigated, but not altogether eliminated.

HHS sought comment from health insurance issuers and other stakeholders on its position that adverse selection related to this special enrollment period will be mitigated by the availability of free or very low-cost coverage with a 94 percent AV and the application of plan category limitations to this new special enrollment period, or whether the adverse selection risk created by this new special enrollment period cannot be sufficiently mitigated such that its creation may result in significant rate increases. HHS also solicited comment regarding whether health insurance issuers and other stakeholders have concerns that the policy could cause any adverse selection among higher-income individuals with variable hours and income. HHS sought comment on whether the requirement that Exchanges verify applicants' projected annual household income post-enrollment, consistent with 45 CFR 155.320(c), is sufficient, or if there are other measures HHS should put in place to further protect program integrity. HHS also solicited comment on estimated implementation burdens for Exchanges that elect to provide this additional enrollment opportunity, including whether implementation of this special enrollment period will be possible in time for consumers to benefit from it during the 2022 plan year. HHS requested comment on whether issuers will have sufficient time to adjust rate filings to account for any increased risk and whether state regulators will have sufficient time to review those filings after a final rule is issued.

HHS further requested comment on whether this proposed special enrollment period should be available indefinitely (as proposed), or whether it should be time-limited. For example, HHS sought comment on whether HHS should finalize the proposed special enrollment period to be available only for coverage during years when enhanced APTC benefits are also available, as provided by the section 9661 of the ARP or any subsequent statute. Finally, HHS requested comment on strategies for providing outreach and education for consumers who may be eligible for this special enrollment period, in particular to help qualifying individuals understand and take advantage of the free or very low-cost coverage that is available to them. Within this group, HHS requested

comments on strategies for educating consumers who qualify to enroll in a 94 percent AV silver plan about the benefits of enrolling in such a plan even if they are required to pay a small premium, as opposed to electing a premium-free bronze plan with a lower AV.

The following is a summary of the comments received and HHS's responses regarding the proposals related to the monthly special enrollment period for APTC-eligible qualified individuals with a household income no greater than 150 percent of the FPL and whose applicable percentage therefore is zero (§ 155.420(d)(16)).

Comment: Many commenters supported the proposal to provide a monthly special enrollment period to APTC-eligible individuals with projected annual household income no higher than 150 percent of the FPL, and a number of them agreed with and expanded upon HHS's position that it would positively impact health equity. For example, several commenters agreed that lower-income individuals often face greater barriers to enrollment, such as a lack of an internet connection or other computer equipment, limited available time due to working multiple jobs, and LEP. Commenters also noted that this group of consumers is disproportionately made up of people of color. Several commenters noted that they expected this special enrollment period to be especially helpful to individuals in their area whose income is under 100 percent of the FPL, but who do not qualify for Medicaid because of their immigration status, and who therefore may qualify for APTC. They noted that this group can be difficult to reach through outreach and education, and therefore may benefit significantly from additional opportunities to enroll throughout the year. Several commenters voiced support for outreach and education to promote awareness of this special enrollment period as well as other special enrollment period qualifying events. Some added that currently-available enrollment opportunities are underutilized due to their complexity and due to the challenges associated with learning about and enrolling in coverage. Some commenters encouraged CMS to focus outreach and education efforts on vulnerable communities, individuals with LEP, immigrants, and the LGBTQ+ community. A few commenters specified potential outreach strategies, such as engaging schools and community health workers.

Response: As discussed in the proposed rule, HHS agrees that

⁷² See the proposed rule at 86 FR 35206 through 35207 for more detail on this discussion.

providing a monthly enrollment opportunity for certain low-income consumers will increase the likelihood that more of these consumers are able to access coverage in spite of barriers that this group, which disproportionately includes people of color, often face. A May 2021 report by the Kaiser Family Foundation estimates that there are approximately 10.9 million uninsured people who are both eligible for coverage through the Exchange and eligible for subsidies under the ACA and ARP.⁷³ The report found that compared to the general non-elderly population in the U.S., this population is more likely to be Hispanic, people with a high school diploma or less, and young adults ages 19 to 34. Additionally, it found that uninsured people eligible for subsidies are more likely to live in rural areas and lack internet access than the general non-elderly population in the U.S. The report also noted that the estimated 6 million uninsured people who may be eligible for a zero-dollar premium plan through the Exchange after application of APTC are more likely to be non-English speakers at home. Providing a monthly enrollment opportunity will give this population of uninsured people more opportunities to access coverage and provide more time for targeted outreach to consumers who may be harder to reach and enroll, such as those who are non-English speakers at home. HHS agrees with commenters' support for robust outreach and education efforts targeted in particular to ensuring awareness and understanding of this special enrollment period and other enrollment opportunities, and will continue to work with stakeholders to develop and optimize targeted messaging.

Comment: Some commenters who supported the proposed special enrollment period were skeptical that it would pose a significant adverse selection risk, citing as mitigating factors the high rate of subsidization for qualifying individuals and the likelihood that younger, healthier individuals would enroll. Many of these commenters also cited comparable state experiences as evidence of the low likelihood of adverse selection and high likelihood of a positive impact on reducing uninsured rates should CMS finalize the proposed special enrollment period. Some commenters said that

State Exchange data on risk factors associated with enrollees who accessed coverage through a special enrollment period, including the special enrollment period that State Exchanges provided during the 2020 or 2021 plan years due to the COVID-19 pandemic, indicated that these enrollees did not pose significant additional risk. One of these commenters asked that CMS analyze data on special enrollment period enrollees in states that use the *HealthCare.gov* platform, and suggested that such analysis would yield a similar result.

For example, multiple commenters cited the Massachusetts State Exchange's enrollment opportunity for individuals with a household income no higher than 300 percent of the FPL, and the ability of consumers up to 200 percent of the FPL to enroll in the Basic Health Program year-round in Minnesota and New York. Specifically, one commenter noted that in Massachusetts, consumers with household incomes up to 300 percent of the FPL may qualify for coverage with low or no monthly premiums, low copays, and no deductibles through the state's Health Connector's ConnectorCare program, and that these individuals, once determined eligible for ConnectorCare, qualify for a 60-day special enrollment period to enroll in coverage at any point during the plan year. The commenter added that in spite of this flexible enrollment opportunity, the state has not experienced individual market adverse selection within the program, and enrollment in the program has remained stable over time. In fact, the commenter noted that the average risk score for insurers participating in ConnectorCare is lower than the risk score for insurers in their individual market outside of ConnectorCare. Finally, the commenter noted a low rate of changes in plans among current enrollees during the mid-2021 enrollment period that the state established due to the COVID-19 pandemic, adding that this experience suggests less risk of adverse selection due to current enrollees changing plans in response to an emerging medical need.⁷⁴

Another commenter cited reports that indicated issuers had not found evidence of adverse selection due to the ability of individuals with a household income up to 200 percent of the FPL to enroll year-round in a Basic Health

Program in New York or Minnesota.⁷⁵ This commenter also cited a report that suggested, based on data from states that offered a mid-year special enrollment period in 2020 due to the COVID-19 pandemic, that these enrollment periods resulted in individuals enrolling who were younger and healthier than those who enrolled during the annual open enrollment period.⁷⁶ Another commenter provided data from DC Health Link, the Washington, DC State Exchange, that indicated that a higher percentage of younger enrollees accessed coverage through the mid-2020 special enrollment period than through the annual open enrollment period.

However, some commenters did not support finalizing this special enrollment period, primarily due to concerns that it posed significant adverse selection risks. Several of these commenters said that in the proposed rule, CMS significantly underestimated the increase in rates due to adverse selection that would result from the proposed special enrollment period. Commenters also raised the concern that qualifying individuals would learn about their enrollment opportunity due to experiencing a health event, and a few also worried that consumers would decline to renew coverage once a medical need had ended, or lose coverage because of the need to pay even a relatively small premium. Commenters also voiced concerns specifically about adverse selection the proposed special enrollment period could create for plans with broad provider networks due to the potential for qualifying enrollees to change plans mid-year to access a specific provider or prescription drug. Some of these commenters were concerned that health care providers would encourage current enrollees to change plans based on an emerging health care need, in order to access coverage for items or services furnished by a provider that does not participate in the consumer's current plan's network. Several commenters added that due to these adverse selection risks, the proposed special enrollment period would result in narrower networks and fewer choices for consumers.

⁷⁵ See Improving the Affordability of Coverage through the Basic Health Program in Minnesota and New York, Kaiser Family Foundation, Dec. 8, 2016, available at <https://www.kff.org/report-section/improving-the-affordability-of-coverage-through-the-basic-health-program-in-minnesota-and-new-york-issue-brief/>.

⁷⁶ See Many States with COVID-19 Special Enrollment Periods See Increase in Younger Enrollees, The Commonwealth Fund, Jan. 28, 2021, available at <https://www.commonwealthfund.org/blog/2021/many-states-covid-19-special-enrollment-periods-see-increase-younger-enrollees>.

⁷³ Kaiser Family Foundation. A closer look at the uninsured marketplace eligible population following the American Rescue Plan Act. May 2021. <https://www.kff.org/private-insurance/issue-brief/a-closer-look-at-the-uninsured-marketplace-eligible-population-following-the-american-rescue-plan-act/>.

⁷⁴ Specifically, the commenter stated that 0.23 percent of Health Connector members changed plans from June to July 2021.

Other concerns included the likelihood that adverse selection would drive up rates and that these rate increases would disproportionately impact unsubsidized consumers. Additionally, several commenters agreed that, as noted in the proposed rule, adverse selection and related increases in individual health insurance premiums would vary significantly by state based on specific market conditions such as Medicaid expansion status. Several commenters, including some that supported the proposal, asked that CMS monitor the individual market for impacts of adverse selection, and one commenter asked us to engage in additional rulemaking if evidence of significant adverse selection is found. A few commenters were also concerned that the applicable risk adjustment methodology would not adequately compensate issuers for individuals who enroll through the special enrollment period and, as a result, have partial-year or short enrollment terms.

Response: HHS agrees that, in many cases, special enrollment periods may encourage consumers who are younger and healthier than average to enroll. Additionally, HHS acknowledges that some Exchanges that have expanded enrollment opportunities for consumers with a projected annual household income below a certain threshold have not experienced significant negative impacts from adverse selection. However, HHS appreciates concerns that the risk of adverse selection may vary significantly based on market conditions specific to different Exchanges, and HHS's goal is also to achieve a balanced approach that takes into account these varying conditions as much as possible. Therefore, HHS is finalizing this special enrollment period as proposed but limiting it to be available only during periods of time during which APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero.

HHS believes that the time-limited nature of this special enrollment period, and providing Exchanges with flexibility in terms of whether to implement it, will help to mitigate concerns about adverse selection, especially when combined with robust outreach and education efforts to maximize the number of qualifying individuals who gain coverage through the special enrollment period based on an understanding of its availability as opposed to due to an emerging health care need.

HHS also appreciates concerns about the impact of rate increases on unsubsidized enrollees and will work

with stakeholders to monitor the markets to track potential adverse selection impacts of the special enrollment period. Currently, however, HHS is of the view that the enhanced benefits available under the ARP mitigate adverse selection risk such that premiums for subsidized and unsubsidized consumers will rise no more than 0.5 to 2 percent as a result of this special enrollment period. In assessing the impact on unsubsidized consumers, HHS also considered that under section 9661 of the ARP, consumers may qualify for premium tax credits at any point at which they would be required to contribute more than 8.5 percent of their annual household income to their benchmark health insurance plan. However, HHS will work with stakeholders to monitor and evaluate the impacts of this policy on individuals who do not qualify for PTC (or who qualify for a maximum amount of zero dollars of PTC), including consideration of possible approaches to address them as may be necessary.

Finally, HHS notes that the HHS-operated risk adjustment methodology added enrollment duration factors to the adult risk adjustment models starting with the 2017 benefit year.⁷⁷ These enrollment duration factors are used in the calculation of adult enrollee risk scores under the state payment transfer formula to account for additional risk associated with enrollees with partial-year enrollment.⁷⁸ They do so through a set of 11 enrollment duration binary indicatory variables that signify that an enrollee had exactly one to 11 months of enrollment in a given plan.⁷⁹ The value of these indicators decreases monotonically from one to 11 months, reflecting the increased annualized costs associated with fewer months of enrollment. Adult enrollees who enrolled during this special enrollment period will receive the applicable risk adjustment enrollment duration factor in the risk score calculation. While HHS

continues to evaluate the current enrollment duration factors, HHS generally disagrees with comments asserting the risk adjustment methodology does not adequately address partial year enrollees.⁸⁰

Comment: Some commenters voiced the concern that providing this open-ended enrollment opportunity would undermine the goal of continuous coverage, decreasing issuers' ability to connect with beneficiaries and making it less likely that certain qualifying consumers would take advantage of preventive care. A few added the concern that consumers changing plans mid-year might not realize their deductibles and other accumulators would reset, and unexpectedly would end up paying more out-of-pocket than if they had remained enrolled in the same plan. Some commenters were concerned about individuals attesting to a lower-than-accurate annual household income in order to gain coverage, and one commenter added the concern that these consumers would unexpectedly have to pay back APTC at tax time for which they were not eligible based on actual annual household income. Some commenters suggested that qualifying enrollees might decide to change plans in spite of the knowledge that their accumulators would reset, with one commenter noting that the relatively low deductible and other cost-sharing requirements for a plan with a 94 percent AV were not a sufficient incentive for enrollees to preserve progress they had made towards meeting maximum cost-sharing requirements. Finally, a few commenters said that HHS does not have statutory authority to establish the proposed special enrollment period, because section 1311(c)(6) of the ACA refers to specific qualifying events and HHS has limited authority to establish special enrollment periods that are not included in this list.

Response: HHS disagrees that this special enrollment period opportunity will discourage eligible consumers from maintaining continuous coverage once they have learned about and been able to access the free or low-cost coverage available to them. In HHS's view and based on State Exchanges' experiences, it is more likely that consumers who newly gain access to free or low-cost coverage through this special enrollment period will maintain such coverage because of its affordability and comprehensiveness. HHS appreciates

⁷⁷ See 81 FR at 94071–94074. Since the 2017 benefit year, HHS has operated the risk adjustment program in all 50 states and the District of Columbia. Massachusetts ran its own risk adjustment program for benefit years 2014–2016. See, e.g., page 5 of the March 2016 Risk Adjustment Methodology White Paper (March 24, 2016), available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

⁷⁸ For more information on the enrollment duration factors, see 85 FR at 7103, 7104.

⁷⁹ See, e.g., *Enrollment Duration Factors* in Table 2: Final Adult Risk Adjustment Factors for 2017 Benefit Year, 81 FR at 94088; and *Enrollment Duration Factors* in Table 1: Final Adult Risk Adjustment Factors for 2022 Benefit Year, available at <https://www.cms.gov/files/document/updated-2022-benefit-year-final-hhs-risk-adjustment-model-coefficients-clean-version-508.pdf>.

⁸⁰ HHS proposed but did not finalize updates to the enrollment duration factors in the 2022 Payment Notice. See 86 FR at 24151–24162. Also see 85 FR at 78581–78586.

concerns that consumers who are enrolled in Exchange coverage may not be aware that changing plans mid-year will cause their deductible and other accumulators to reset, and HHS will continue working to develop and enhance messaging to make consumers and other stakeholders, such as enrollment assisters, understand that this is the case. HHS disagrees that qualifying enrollees with a 94 percent AV silver plan will not have an incentive to preserve progress they make during the year toward meeting their deductible and other cost-sharing requirements, because for enrollees who qualify for income-based CSRs, the deductible and cost-sharing requirements under the plan variation is based on household income, and such amounts therefore likely do not represent insignificant amounts relative to that household income.

HHS notes that consumers who apply for Exchange coverage on *HealthCare.gov* are required to attest multiple times, at the beginning and end of the application process, that the information they have provided is correct.⁸¹ As part of the implementation of this special enrollment period, HHS will also continue to emphasize to applicants and current enrollees the importance of attesting to an accurate and up-to-date estimate of their annual household income. Additionally, when applicants attest to a household income amount that CMS cannot verify using a trusted data source, HHS generates an income “inconsistency” explaining that this is the case and requiring the consumer to submit additional information. This process involves extensive outreach and education, which helps ensure that consumers understand the importance of attesting to an accurate household income amount, including how their attested household income informs the APTC that they receive. Further, once the special enrollment period has been implemented, HHS will monitor uptake and the occurrence of income inconsistencies among qualifying individuals, and work with stakeholders as appropriate to address instances of potential abuse. Finally, as discussed in prior rulemaking, section 1311(c) of the ACA requires the Secretary to establish the minimum uniform enrollment periods across all Exchanges; and section 1321(a) of the ACA provides

broad authority for the Secretary to issue regulations setting standards to implement the statutory requirements related to Exchanges, QHPs, and other standards under title I of the ACA.⁸²

Comment: Several commenters raised the concern that HHS underestimated rate increases due to the proposed special enrollment period, and that issuers had not incorporated this risk into their rates for the 2022 plan year. However, no commenters recommended giving issuers an additional opportunity to adjust rates—one did not believe such an opportunity was needed, and the others did not believe that there was enough time for issuers to submit and regulators to review updated rates before the 2022 plan year. One commenter requested that HHS delay making the proposed special enrollment period available until the 2023 plan year in order to provide issuers with adequate time to incorporate related risk into their rates. Some commenters who did not support the special enrollment period suggested that, if it were to be finalized, it should be limited to the first few months of the year. These commenters noted that the tax season could be leveraged to promote the special enrollment period, and that this limitation was reasonable because consumers should be able to accurately predict their annual income once they have completed the Federal income tax filing process.

Response: Because of the benefit to consumers who are eligible for free or very low-cost coverage provided by enhanced APTC through the ARP from having additional opportunities to enroll in Exchange coverage while this enhanced assistance is in place, HHS is finalizing the special enrollment period to be available for the 2022 plan year. However, HHS is limiting it to be available only during periods of time during which APTC benefits are available such that the applicable taxpayers’ applicable percentage is set at zero. Further, HHS appreciates concerns that issuers and other stakeholders benefit from having as much time as possible to adjust rates and other planning processes based on upcoming developments. However, in some instances, particularly in the context of a PHE such as the COVID–19 pandemic, HHS believes that rapid responses are warranted and necessary to help ensure as many individuals as possible can access basic necessities such as health insurance coverage and care. Further, HHS believes it is appropriate to provide this special enrollment period

for the full duration of time that enhanced APTC benefits are available in order to maximize opportunities for qualifying individuals to enroll. Finally, while the Federal income tax filing process may be helpful for some consumers as a way to estimate their annual household income, HHS notes that this is not necessarily the case, because the Federal income tax filing process is based on prior year household income, and applicants for future or current year Exchange coverage with financial assistance must estimate their household income for the upcoming or current coverage year, and annual household income can fluctuate significantly from one year to another.

Comment: Several commenters that opposed the special enrollment period due to concerns about adverse selection and resulting rate increases said that, if finalized, they strongly supported applying plan category limitations as proposed. Some of these commenters also recommended that qualifying individuals be limited even further; for example, to a specific plan or plans such as the second lowest-cost or lowest-cost silver plan available to them, or to a plan with an AV of 94 percent. Some commenters expressed stronger concerns about adverse selection due to enrollees changing plans based on provider network rather than based on metal level. Some commenters asked that only currently uninsured consumers be permitted to use the special enrollment period, or that consumers only be permitted to access the special enrollment period once per year, or if they had not yet received any APTC for the year, in order to help mitigate adverse selection.

Response: As discussed in the proposed rule, HHS believes that applying plan category limitations to this special enrollment period will help to mitigate adverse selection, because it will limit the ability of enrollees to change to a higher metal level plan based on a new health care need and then change back to a silver plan once the health issue is resolved. Further, HHS notes that all consumers who qualify for this special enrollment period and choose to enroll in a silver-level plan will gain coverage with a 94 percent AV based on their projected annual household income level. HHS does not believe that it is necessary to limit enrollees to one or several specific silver-level plan(s), because HHS believes that enrollees who are interested in changing plans during the year will generally be deterred as such a change will often mean they lose progress they have made toward meeting their deductible and other

⁸¹ For example, before signing and submitting their application, all consumers see the statement, “I’m signing this application under penalty of perjury, which means I’ve provided true answers to all of the questions to the best of my knowledge. I know I may be subject to penalties under Federal law if I intentionally provide false information.”

⁸² See, for example, 77 FR 18310, 18312 (Mar. 27, 2012), and 78 FR 42160, 42162 (July 15, 2013).

accumulators. Additionally, requiring this type of restriction, limiting use of the special enrollment period to once per year per consumer, or limiting the special enrollment period to consumers who had not yet received APTC during the applicable plan year, would impose additional complexity on Exchanges to the point that implementation would not be possible in time for the 2022 plan year. However, in consideration of these concerns, HHS is clarifying at § 155.420(a)(4)(ii)(D) that an enrollee who is adding a qualified individual or dependent may add the newly-enrolling household member to their current QHP; or, change to a silver-level QHP and add their newly-enrolling household member to this silver-level QHP; or, change to a silver-level QHP and enroll the newly-enrolling qualified individual or dependent in a separate QHP. HHS believes that this language is appropriate to provide clarity on options and limitations for enrollees whose household members newly enroll through this special enrollment period. In particular, this language clarifies that, while newly-enrolling qualified individuals and dependents are not subject to plan category limitations, current enrollees with a newly-enrolling dependent or other household member may not use this new special enrollment period to change to a plan of any metal level along with their newly-enrolling household member.

Comment: One commenter misunderstood the proposal to newly permit enrollees to change from one metal level to another, and raised concerns about how such changes could affect enrollment in standalone dental plans. Another commenter asked for clarification that individuals will still qualify for the other special enrollment periods only when they experience a special enrollment period qualifying event that makes them eligible.

Response: HHS clarifies that this proposal, and the resulting final rule, do not newly permit Exchange enrollees to change to a plan of a different metal level or make policy changes to plan category limitations for existing special enrollment periods. Rather, the new rule establishes a plan category limitation to address a newly-created special enrollment period triggering event and makes a small technical clarification to the preceding paragraph, as further discussed earlier in this preamble. Further, HHS has discussed and extensively investigated concerns about accidental standalone dental plan disenrollment due to a change in medical QHP and has not found this to be a problem in practice for *HealthCare.gov* enrollees, who are

always offered the opportunity to select or re-select their standalone dental plan after completing medical QHP selection. Finally, HHS clarifies that the new monthly special enrollment period does not change or expand eligibility requirements for other special enrollment period qualifying events at § 155.420(d).

Comment: A few commenters asked that HHS require pre-enrollment verification of income for consumers to qualify for this special enrollment period. However, several commenters supported the proposal not to require such verification, and one commenter encouraged HHS to monitor even post-enrollment income verification to ensure that it did not present a significant barrier to low-income consumers seeking to enroll in coverage.

Response: As discussed in the proposed rule, HHS believes that the post-enrollment income verification process already in place consistent with § 155.320(c) is sufficient to ensure program integrity, because consumers who do not verify their attested household income through the post-enrollment verification process will have their APTC adjusted accordingly. Further, HHS agrees with commenters' concerns that imposing a pre-enrollment income verification process would prevent eligible consumers from accessing coverage through the special enrollment period, especially those who represent marginalized communities that face barriers to accessing documentation quickly and those who are younger and healthier, and therefore, have less incentive to devote time to a complex enrollment process.

Comment: Some commenters that did not have adverse selection concerns asked HHS not to finalize the proposed special enrollment period to be limited to the period of time during which enhanced APTC is available per ARP or other statutory authority. These commenters' position was that even without the ARP's enhanced APTC, consumers with household income below a certain FPL are heavily subsidized enough to mitigate adverse selection. However, commenters with concerns about adverse selection, including some who otherwise supported offering the special enrollment period as proposed, requested that, if finalized, CMS limit its availability to periods when APTC is available at the level provided for under the ARP.

Response: To an extent, HHS agrees with certain commenters that some markets could see limited effects of adverse selection if the proposed special enrollment period were available

permanently, depending on individual market conditions. However, as discussed in the proposed rule, HHS believes that that access to 94 percent AV coverage premium-free or at very low-cost after application of APTC will help to mitigate risk of adverse selection, because qualifying individuals will not have an incentive not to enroll or to end coverage when health care services are no longer needed. HHS also agrees with commenters' concerns that even a relatively small premium could introduce additional risk of adverse selection. Therefore, HHS is finalizing this special enrollment period to be available only during periods of time during which APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP.

Comment: Several issuers provided recommendations for alternatives to the proposed special enrollment period that would assist consumers with transitioning between Medicaid and Exchange coverage—for example, a few commenters suggested providing an extended loss of coverage special enrollment period window to those who lose Medicaid coverage due to the end of the COVID-19 PHE. Other suggestions included establishing policy similar to a Medicaid waiver in New York under section 1115 of the Social Security Act that allows issuers who are Medicaid Managed Care Organizations (MCOs) to assist consumers with re-enrollment, and suggested that HHS permit MCOs to auto-enroll consumers eligible to transition into a corresponding QHP, or generally facilitate enhanced communication between issuers and enrollees to allow issuers to provide more support for transitions. One commenter suggested that instead of providing this special enrollment period, HHS automatically enroll all qualifying individuals into coverage with the option to opt out. One commenter supported the proposed special enrollment period but also offered suggestions for improving consumers' transition from Medicaid to Exchange coverage. Another commenter who supported the proposed special enrollment period requested that, in addition, HHS also provide guidance in rulemaking on an "Automatic Retention" program that would automatically enroll individuals who miss premium payments into a plan available without premiums after application of the APTC until they lose eligibility or cancel their plan.

Response: As discussed in the proposed rule, HHS believes that providing a special enrollment period for all APTC-eligible individuals with a household income up to 150 percent of the FPL, and whose applicable percentage is therefore set at zero, will be an important tool to help these consumers access coverage. However, HHS also appreciates the interest in developing additional strategies for improving the transition from Medicaid to Exchange coverage and encouraging newly enrolling individuals and current enrollees to maintain continuous coverage, and HHS will continue to work with stakeholders in the future to do so.

Further, HHS notes that there are other existing special enrollment periods that may support Medicaid beneficiaries' transition to Exchange coverage at the end of the COVID-19 PHE. For example, if state Medicaid programs or Medicaid MCOs experience delays in delivering notices informing beneficiaries that their Medicaid eligibility is terminating, Exchanges currently have flexibility and authority to provide additional relief for consumers who lose Medicaid coverage. As discussed in the proposed rule,⁸³ Exchanges could provide consumers who do not timely learn of their opportunity to enroll in Exchange coverage with additional time to enroll in health coverage based on the regulation at § 155.420(c)(5), recently finalized in part 2 of the 2022 Payment Notice final rule. Additionally, § 155.420(d)(9) provides a special enrollment period to consumers who demonstrate to the Exchange, in accordance with guidelines issued by HHS, the individual meets exceptional circumstances as the Exchange may provide. In the FFE and FF-SHOP Enrollment Manual, which provides operational policy and guidance on key topics related to eligibility and enrollment for FFEs and SBE-FPs, HHS explains that an individual may qualify for a special enrollment period through authority at § 155.420(d)(9) if their enrollment or non-enrollment in a QHP (or that of their dependent) is the result of an exceptional circumstance, as determined by the Secretary.⁸⁴ In 2018, HHS issued guidance to provide that an individual or their dependents who are affected by an emergency or major disaster that is recognized with a formal declaration from the Federal Emergency

Management Agency (FEMA) and that prevents the qualified individual or their dependents from enrolling during the annual open enrollment period or during the enrollment window for a special enrollment period for which they qualified will be eligible for an Exceptional Circumstances special enrollment period under § 155.420(d)(9). If needed, HHS will similarly provide a special enrollment period to former Medicaid beneficiaries who are prevented from enrolling in Exchange coverage by challenges they experience as a result of the end of the PHE, and HHS notes that State Exchanges can also take similar action. Further, HHS will continue to engage with all Exchanges and other stakeholders to provide additional support for consumer transitions between Medicaid and Exchange coverage following the end of the PHE.⁸⁵ HHS believes the special enrollment period finalized in this rule, along with existing special enrollment authorities granted to Exchanges discussed here, are sufficient to ensure that consumers who lose Medicaid coverage due to the end of the PHE are able to transition to Exchange coverage.

Comment: Multiple commenters that supported the proposal were optimistic about Exchanges' ability to implement it in time for the 2022 plan year based on availability of comparable special enrollment periods in some Exchanges, such as Massachusetts'. Other commenters were generally supportive of the special enrollment period, but strongly supported that it be finalized, as proposed, at the option of the Exchange, and varied in their assessments of level of effort to implement it. One estimated that the special enrollment period could be implemented for the 2022 plan year, but that state regulators would first need to be consulted about potential impact on individual market rates to determine whether they should. One commenter did not think that Exchanges could implement the special enrollment period in time for the 2022 plan year, and another was unsure about whether they could do so.

⁸³ For example, in 2018, HHS issued guidance to provide that an individual or their dependents who are affected by an emergency or major disaster that is recognized with a formal declaration from FEMA and that emergency or major disaster prevents the qualified individual or their dependents from enrolling during the annual open enrollment period or during the enrollment window for a special enrollment period for which they qualified will be eligible for an exceptional circumstances special enrollment period under § 155.420(d)(9). See <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/8-9-natural-disaster-SEP.pdf>.

Finally, several commenters said that the special enrollment period could be implemented in time for the 2022 plan year, but without plan category limitations, and suggested that these limitations be optional for Exchanges due to significant additional level of effort for implementation, and because of the likely very small affected population. One state regulator requested that plan category limitations not be applied because some qualifying individuals would be better served by enrolling in a very low-cost bronze plan, and that they should be permitted to determine with an agent or broker which metal level was best for them.

Response: HHS agrees with commenters that State Exchanges should have the option of whether to implement this special enrollment period, and therefore have finalized, as proposed, that it be at the option of the Exchange. While HHS understands concerns about complexity of implementation, in consideration of strong support from other commenters for guardrails to help mitigate adverse selection, HHS agrees that the proposed plan category limitations, as clarified in this final rule, will be helpful in mitigating potential adverse selection, even in Exchanges in which the population of consumers potentially eligible for this special enrollment period is small.

Comment: Based on a belief that adverse selection would be limited and that the uninsured rates would decrease due to the proposed special enrollment period, several commenters asked that HHS increase the household income threshold for qualifying individuals to 200 or 250 percent of the FPL. These commenters' rationale was that individuals with household income below this threshold are also highly subsidized to an extent that would mitigate adverse selection risk. Several commenters also noted that this income range would include more consumers who make minimum wage, and who regularly transition between Medicaid and Exchange coverage.

Response: HHS shares the goal of reducing barriers to coverage for as many individuals as possible. However, as discussed in the proposed rule, HHS believes that access to premium-free or very low-cost coverage with a 94 percent AV after application of APTC and CSRs will be an important factor to help mitigate risk of adverse selection, because qualifying individuals will not have an incentive not to enroll or to end coverage when health care services are no longer needed. While many individuals with projected annual household income greater than 150

⁸³ See 86 FR 35170.

⁸⁴ See FFEs and FF-SHOP Enrollment Manual: Section 6, Exhibit 14, https://www.regtap.info/uploads/library/ENR_FFEFFSHOPEnrollmentManual2020_5CR_090220.pdf.

percent of the FPL also benefit from APTC that covers a significant portion of their monthly premium, given a number of commenters' concerns about adverse selection risk, HHS believes it is appropriate to make the special enrollment period available only to individuals whose applicable taxpayer has an applicable premium percentage set at zero. Limiting the special enrollment period in this way also ensures that eligible individuals will have access to a silver plan with a 94 percent AV, which may reinforce qualifying individuals' interest in maintaining coverage when health care services are no longer needed, even for those who must pay a small premium, because of the ability to access care without significant cost sharing.

Further, as also addressed in the proposed rule, adverse selection risk presented by the proposal stems, in part, from qualifying individuals who live in states where premiums for Exchange coverage cannot be fully paid for with APTC, such that these individuals will not have access to a silver plan with a zero-dollar premium, because these individuals may have more incentive to end their coverage when they no longer believe that they need it, or to inadvertently allow their coverage to lapse due to missing multiple premium payments. Therefore, HHS is finalizing the special enrollment period for APTC-eligible individuals with a household income up to 150 percent of the FPL, but limiting it to be available only during periods of time during which APTC benefits are available, such that the applicable taxpayers' applicable percentage is set at zero.

6. Clarification of Special Enrollment Periods for Enrollees Who Are Newly Eligible or Newly Ineligible for Advance Payments of the Premium Tax Credit (§ 155.420(f))

HHS proposed new language to clarify that, for purposes of the special enrollment period rules at § 155.420(d), references to ineligibility for APTC refer to being ineligible for such payments or being technically eligible for such payments but qualifying for a maximum of zero dollars per month of such payments. That is, a qualified individual, enrollee, or his or her dependent who is technically eligible for APTC because they meet the criteria at § 155.305(f), but who qualifies for a maximum APTC amount of zero dollars, is also considered ineligible for APTC for purposes of these special enrollment periods, even if they experience a change in circumstance from an APTC ineligible status in accordance with § 155.305(f), such as having other MEC.

As discussed in the proposed rule, currently, the special enrollment periods to which this clarification is applicable are the triggering events at § 155.420(d)(6), but HHS proposed that the clarification apply to all of § 155.420 to ensure consistency, for example, between special enrollment period triggering events at § 155.420(d) and related coverage effective date and enrollment window rules at § 155.420(b) and (c), respectively. After consideration of public comments, as further discussed below, HHS is finalizing § 155.420(f) as proposed.

As discussed in the proposed rule, IRS rules at 26 CFR 1.36B–3 govern the APTC amount an individual may receive once they are found eligible for APTC under § 155.420(d)(6). Pursuant to these IRS rules, an Exchange enrollee's monthly APTC amount is the excess of the adjusted monthly premium for the applicable benchmark plan⁸⁶ over $\frac{1}{12}$ of the product of the taxpayer's household income and the applicable percentage for the taxable year. Under this formula, if the applicable percentage of $\frac{1}{12}$ of a taxpayer's estimated annual household income is higher than the adjusted monthly premium of the relevant benchmark plan, a taxpayer will be eligible generally for APTC under § 155.305(f)(1), but will qualify for a maximum APTC amount of zero dollars under 26 CFR 1.36B–3. Currently, neither § 155.305(f)(1) or 26 CFR 1.36B–3 recognize or explain that an individual generally could be APTC-eligible, but not qualify to receive any amount in APTC greater than zero. The current text of § 155.420 similarly does not address this issue, such that there could exist some ambiguity about what it means to be APTC-eligible or ineligible for purposes of the special enrollment periods under § 155.420.

HHS proposed to add text to § 155.420 to clarify that an individual who qualifies for a maximum APTC amount of zero dollars is considered ineligible for APTC for purposes of the § 155.420 special enrollment periods. Specifically, any determination that an individual cannot receive an APTC amount greater than zero dollars is equivalent to being found APTC-ineligible for purposes of special enrollment period eligibility under § 155.420(d). HHS noted that HHS believed this interpretation comports with the perspective of an

⁸⁶ Per IRS rules at 26 CFR 1.36B–3(f), the term “benchmark plan” is generally used to refer to the second lowest-cost silver plan, as described in section 1302(d)(1)(B) of the ACA (42 U.S.C. 18022(d)(1)(B)), offered to the taxpayer's coverage family through the Exchange for the rating area where the taxpayer resides.

applicant for Exchange coverage who will take their available financial assistance amount into account when selecting a QHP for the upcoming coverage year and who may wish to change their QHP partway through a coverage year because of a change in their financial assistance. Because HHS believes that the current regulation permits this interpretation, but could instead be interpreted to require strict adherence to the listed requirements for APTC eligibility at § 155.305(f) (which does not address situations where a consumer meets these requirements but qualifies for a zero-dollar APTC amount), HHS proposed regulation text to ensure consistent and correct interpretation of what it means to be determined ineligible for APTC. This reading of APTC ineligibility is also consistent with HHS's discussion of the policy in previous rulemaking. For example, in the 2020 Payment Notice final rule,⁸⁷ HHS added a new paragraph at § 155.420(d)(6)(v) allowing Exchanges to provide a special enrollment period for qualified individuals who experience a decrease in household income and receive a new determination of eligibility for APTC by an Exchange, and who had MEC for one or more days during the 60 days preceding the financial change.

HHS stated that HHS believes that this clarification will be especially helpful in light of the removal of the upper APTC eligibility limit on household income at 400 percent of the FPL for taxable years 2021 and 2022 under the ARP.⁸⁸ This is because, with this change, any applicants with household incomes over 400 percent of the FPL may be eligible for APTC, so more consumers likely will qualify for APTC technically, but for an APTC amount of zero dollars. This clarification ensures that special enrollment period regulations clearly reflect that enrollees for whom this is the case may qualify for a special enrollment period based on a decrease in their household income, or any other change that makes them newly eligible for an APTC amount of greater than zero dollars.

HHS explained that HHS believes that this clarification should also apply to the special enrollment periods provided in § 155.420(d)(6)(iii) through (v), which include special enrollment periods for individuals who become newly eligible for APTC. However, HHS sought comment on whether the clarification that a qualified individual, enrollee, or his or her dependent is considered

⁸⁷ 84 FR 17526.

⁸⁸ Public Law 117–2.

APTC-ineligible if they meet the requirements at § 155.305(f), but qualify for a maximum APTC amount of zero dollars, should be applied as proposed to all of the special enrollment period qualifying events at § 155.420(d)(6), or whether it should be limited to only apply to some of them. For example, HHS sought comment on whether HHS should only apply this clarification to the special enrollment periods at § 155.420(d)(6)(i) and (ii) and (iv) and (v), to permit individuals whose ESC is no longer considered affordable or no longer meets the minimum value standard to qualify for a special enrollment period to enroll in Exchange coverage through § 155.420(d)(6)(iii) regardless of whether they qualify for an APTC amount of greater than zero dollars.

HHS also sought comment on the proposal, including from State Exchanges, regarding whether this definition of APTC eligibility reflects their current implementation of the special enrollment period qualifying events per § 155.420(d)(6), and if not, whether there are policy concerns about this clarification, or the burden of making related changes to Exchange operations. HHS also sought comment on whether HHS should provide Exchanges with flexibility in terms of when they are required to ensure that their operations reflect this definition, and whether Exchanges should be permitted to adopt a more inclusive definition, for example, to consider an individual to be newly eligible or ineligible for APTC for purposes of the special enrollment periods at § 155.420(d)(6) based on a change from a zero-dollar maximum APTC amount to APTC ineligibility for another reason per regulations at § 155.305(f).

The following is a summary of the comments received and HHS's responses regarding these proposals related to the clarification of the special enrollment period for enrollees who are newly eligible or newly ineligible for advance payments of the premium tax credit (§ 155.420(f)).

Comment: Multiple commenters supported this clarification, and one commenter confirmed that it reflected their State Exchange's implementation of the applicable special enrollment periods. Several commenters, including another State Exchange, agreed that this clarification is helpful for mitigating issuer and consumer confusion. However, one commenter raised the concern that the clarification would result in fewer consumers qualifying for a special enrollment period due to confusion about how to report life changes related to special enrollment

period access and eligibility. The commenter added that some consumers who are not receiving PTCs may wish to change plans based on having reported a change to their household income. This commenter also raised the concern that it would require their State Exchange to make significant system and messaging adjustments to change how they implement applicable special enrollment periods.

Response: HHS appreciates comments that this clarification is helpful, and HHS is finalizing it as proposed. In response to the concern that it will cause fewer consumers to qualify for special enrollment periods, HHS notes that in addition to providing general clarity, HHS's primary purpose for this update is to be clear that enrollees may qualify for a special enrollment period at § 155.420(d)(6)(i) or (ii) based on a change from being eligible for a maximum APTC of zero dollars per month to an amount greater than zero dollars per month, or who become newly eligible for a maximum of zero dollars per month after previously having qualified for an amount of more than zero dollars. While this may require some Exchanges to make system changes, HHS is finalizing the clarification as proposed to ensure that enrollees in this situation may qualify for a special enrollment period based on a meaningful change in eligibility for APTC as opposed to a change that is not meaningful.

Additionally, HHS appreciates the comment that some consumers who experience a change in household income mid-year may wish to change to a different QHP based on this clarification. However, current rules do not include special enrollment periods based only on a change in household income, and qualifying events at § 155.420(d)(6) are not based on changes in household income, but rather on changes in eligibility for APTC, to account for whether, based on their household income, a qualifying individual can receive assistance with their monthly QHP premium payments. HHS disagrees that this clarification will result in fewer special enrollment periods for consumers who qualify based on experiencing an established special enrollment period triggering event, because special enrollment period rules at § 155.420(d) do not currently include an enrollment opportunity based solely on a change in household income. However, HHS commits to continue working with State Exchanges on an ongoing basis to mitigate confusion related to eligibility rules to promote greater access to coverage. HHS also commits to

collaborating to promote continuity of coverage for all Exchange enrollees, including by helping enrollees to understand the importance of reporting changes to their household income so that they receive an up-to-date APTC amount even if their change does not make them eligible for a special enrollment period.

Comment: One commenter generally supported the proposal, but requested that HHS finalize it to exempt the special enrollment period at § 155.20(d)(6)(iii) so that employees or dependents who are enrolled in an employer-sponsored plan and determined newly APTC-eligible based in part on a finding that they are no longer eligible for qualifying coverage in an eligible employer-sponsored plan in accordance with 26 CFR 1.36B-2(c)(3) may qualify for a special enrollment period even if they qualify for a maximum payment of zero dollars per month. This commenter explained that individuals in this situation could benefit from an opportunity to change to coverage that meets the minimum value standards that apply to Exchange coverage, even if they are required to pay full price for Exchange coverage.

Response: HHS appreciates this comment and agrees that an individual whose ESC is no longer considered affordable or no longer provides minimum value may wish to access individual market coverage through an Exchange, even if they will not qualify for APTC to help reduce their premiums.

HHS does not agree that additional special enrollment period authority is necessary at this time, because there are existing pathways to enrollment in individual market coverage through an Exchange for many individuals who meet the conditions of the triggering event at § 155.420(d)(6)(iii), except that they do not qualify for APTC. Further, based on HHS's experience, changes to ESC that would have these effects are rarely made mid-plan year. Therefore, employees and dependents who experience this type of change and whose ESC renews on a calendar year basis can enroll in individual market coverage through an Exchange during the annual open enrollment period, and those whose ESC renews on a non-calendar year basis can qualify for a special enrollment period per § 155.420(d)(1)(ii), based on the last day of the plan year of their ESC. In what HHS expects will be rare instances that an individual's ESC ceases to meet the minimum value or affordability standards in the middle of a plan year under circumstances that would not qualify the individual for a special

enrollment period under § 155.420(d)(1)(ii), an Exchange could exercise its authority to find that this change is an exceptional circumstance that qualifies the individual for a special enrollment period under § 155.420(d)(9).

Due to the existing special enrollment period authorities available to Exchanges, HHS is of the view that additional special enrollment period authority is not necessary at this time. HHS will monitor these circumstances and, if necessary, consider proposing such authority in future rulemaking.

C. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. User Fee Rates for the 2022 Benefit Year (§ 156.50)

In the December 4, 2020 **Federal Register** (85 FR 78572), HHS published the proposed 2022 Payment Notice that proposed to reduce fiscal and regulatory burdens across different program areas and to provide stakeholders with greater flexibility that included a proposed 2022 user fee rate. In the January 19, 2021 **Federal Register** (86 FR 6138), HHS published part 1 of the 2022 Payment Notice final rule that addressed a subset of the policies proposed in the proposed rule. That final rule, among other things, finalized the 2022 user fee rates for issuers offering QHPs through the FFEs at 2.25 percent of total monthly premiums, and the user fee rate for issuers offering QHPs through SBE-FPs at 1.75 percent of total monthly premiums.

On January 28, 2021, President Biden issued E.O. 14009,⁸⁹ directing HHS, and the heads of all other executive departments and agencies with authorities and responsibilities related to the ACA, to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether such agency actions are inconsistent with this Administration's policy to protect and strengthen the ACA and to make high-quality health care accessible and affordable for every American. As part of this review, HHS examined policies and requirements under the proposed 2022 Payment Notice and part 1 of the 2022 Payment Notice final rule to analyze whether the policies under these rulemakings might undermine the Health Benefits Exchanges or the health insurance markets, and whether they may present unnecessary barriers to individuals and

families attempting to access health coverage. HHS also considered whether to suspend, revise, or rescind any such actions through appropriate administrative action.

In compliance with E.O. 14009 and as a result of HHS's review of the proposed 2022 Payment Notice and part 1 of the 2022 Payment Notice final rule, HHS discussed in the proposed rule that HHS has reanalyzed the additional costs of expanded services, such as consumer outreach and education in the FFEs and SBE-FPs, and Navigators in the FFEs in 2022. As explained in part 2 of the 2022 Payment Notice final rule,⁹⁰ HHS indicated the intention to propose to increase the user fee rates for the 2022 benefit year in future rulemaking. Therefore, in the proposed rule, HHS proposed new QHP issuer user fee rates for the 2022 plan year: a new FFE user fee rate of 2.75 percent of total monthly premiums, and a new SBE-FP user fee rate of 2.25 percent of monthly premiums. The proposed rates are based on internal projections of Federal costs for providing special benefits to FFE and SBE-FP issuers during the 2022 benefit year, taking into account estimated changes in parameters, specifically the increased funding to the FFE Navigator program and consumer outreach and education. As discussed in the proposed rule, HHS is of the view that pursuit of the proposal was necessary for consistency with E.O. 14009 and this Administration's goal of protecting and strengthening the ACA and making high-quality health care accessible and affordable for every American. HHS noted that HHS believed that expanded outreach and education will lead to broader risk pools, lower premiums, fewer uninsured consumers, and expanded use of Exchange services.

Section 1311(d)(5)(A) of the ACA permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. If a state does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the ACA directs HHS to operate an Exchange within the state. Accordingly, in § 156.50(c), HHS specifies 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 annual 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 where enrollment is through an FFE or SBE-FP. In addition, OMB Circular No. A-25 establishes Federal policy regarding the assessment of user fee charges under other statutes, and applies to the extent permitted by law. Furthermore, OMB Circular No. A-25 specifically provides that a user fee charge will be assessed against each identifiable recipient of special benefits derived from Federal activities beyond those received by the general public.

Activities performed by the Federal Government that do not provide issuers participating in an FFE with a special benefit, or that are performed by the Federal Government for all QHPs, including those offered through State Exchanges, are not covered by this user fee. As in benefit years 2014 through 2021, issuers seeking to participate in an FFE in the 2022 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.

a. FFE User Fee Rate

For the 2022 benefit year, issuers participating in an FFE will receive the benefits of the following Federal activities:

Under Consumer Information and Outreach:

- Provision of consumer assistance tools;
- Consumer outreach and education; and
- Management of a Navigator program.

Under Health Plan Bid Review, Management, and Oversight:

- Certification processes for QHPs (including ongoing compliance verification, recertification, and decertification); and

- Regulation of agents and brokers.
- Under Eligibility and Enrollment:
- Eligibility determinations; and
 - Enrollment processes.

Activities through which FFE issuers receive a special benefit also include use of the Health Insurance and Oversight System (HIOS), which is partially funded by FFE and SBE-FP user fees, and the Multidimensional Insurance Data Analytics System (MIDAS) platform, which is fully funded by FFE and SBE-FP user fees. In light of E.O. 14009,⁹¹ published on January 28, 2021, the administration has a priority to increase accessibility and affordability of health care for every American. Consistent with increasing

⁸⁹ 86 FR 7793 (Feb. 2, 2021).

⁹⁰ 86 FR 24140, 24288.

⁹¹ 86 FR 7793 (Feb. 2, 2021).

accessibility for every American an expanded budget for consumer support activities and Navigators was developed, and HHS conducted additional analytic review which revealed that the user fee rates established in part 1 of the 2022 Payment Notice final rule⁹² need to be increased to sustain essential Exchange-related activities. Based on this new analysis of the increased contract costs and projected premiums and enrollment (including changes in FFE enrollment resulting from anticipated establishment of State Exchanges or SBE-FPs in certain states in which FFEs currently are operating) for the 2022 plan year, HHS proposed to establish the FFE user fee for all participating FFE issuers at 2.75 percent of total monthly premiums.

b. SBE-FP User Fee Rate

As previously discussed, OMB Circular No. A-25 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.

SBE-FPs enter into a Federal platform 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), HHS specifies 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 the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an SBE-FP, unless the SBE-FP and HHS agree on an alternative mechanism to collect the funds from the SBE-FP or state.

The benefits provided to issuers in SBE-FPs by the Federal Government 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 ACA, and QHP enrollment functions under § 155.400. 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 services, and allocating a share of those costs to issuers in the relevant SBE-FPs, as issuers in SBE-FPs receive those special benefits and will be able to access the increased consumer support and education.

Similar to the FFEs, activities through which SBE-FP issuers receive a special benefit also include use of HIOS, which is partially funded by FFE and SBE-FP user fees, and the MIDAS platform, which is fully funded by FFE and SBE-FP user fees. In light of E.O. 14009,⁹³ the administration has a priority to increase accessibility and affordability of health care for every American. Consistent with increasing accessibility for every American, an expanded budget for consumer support activities and Navigators was developed, and HHS conducted additional analytic review which revealed that the user fee rates established in part 1 of the 2022 Payment Notice final rule⁹⁴ need to be increased to sustain essential Exchange-related activities. Based on this new analysis of the increased contract costs and projected premiums and enrollment (including changes in FFE enrollment resulting from anticipated establishment of State Exchanges or SBE-FPs in certain states in which FFEs currently are operating) for the 2022 plan year, HHS proposed to establish the SBE-FP user fee for all participating SBE-FP issuers at 2.25 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE-FP for benefit year 2022.

HHS sought comment on the FFE and SBE-FP user fee rates for 2022. The following is a summary of the comments received and the responses to HHS' proposals related to the FFE and SBE-FP user fee rates for 2022.

Comment: Most commenters supported the proposal to increase the 2022 user fee rates for the FFEs and SBE-FPs. These commenters supported funding increases for consumer outreach and education and Navigators, and for building up the Exchange infrastructure. Other commenters were concerned about changes to user fees happening this late into the 2022 rate-setting process. One commenter suggested that the increased user fee collections be aimed at only consumer outreach and education and not toward funding Navigators.

Response: HHS is finalizing the higher 2022 user fee rates for the FFEs and SBE-FPs as proposed. These higher user fee rates will allow for an expanded budget for consumer support activities and Navigators and will ensure that

HHS can sustain essential Exchange-related activities.

HHS is finalizing the proposal to increase the user fee rates to fund both consumer outreach and education and Navigators. Pursuant to E.O. 14009, HHS is aiming to increase accessibility and affordability of health care for every American. On August 27, 2021, CMS awarded \$80 million in grant funding to 60 Navigator grantees in 30 states with an FFE for the 2022 plan year.⁹⁵ Extending funding for Navigators through 2022 is consistent with increasing accessibility for every American.

HHS also appreciates commenters' concerns about rate-setting. To help stakeholders anticipate a possible increase to the FFE and SBE-FP user fee rates for 2022, HHS announced in part two of the 2022 Payment Notice final rule⁹⁶ that HHS intended to propose increased new user fee rates for 2022 and provided the projected user fee rates that HHS was considering. Therefore, HHS believes that stakeholders may have been anticipating the proposed changes to the 2022 user fee rates and reasonably could have taken steps to accommodate the possible change.

Comment: Some commenters recommended that HHS further increase the user fee rates to 3.5 percent or 3.0 percent of total monthly premiums. Other commenters were concerned about the proposed higher user fee rates. Some of these commenters were concerned that increasing user fee rates is unnecessary as increased enrollment should provide adequate revenue to fund Exchange activities. Other commenters expressed concern that the costs of increased user fee rates would be passed on to consumers in the form of higher premiums. One commenter was concerned that increasing user fee rates could result in reduced commission paid to agents and brokers and limit enrollment growth through those channels. Another commenter suggested that, rather than increasing user fee rates, HHS should use excess collections from prior years to cover the costs of the expanded Navigator and consumer information and outreach activities. One commenter observed that the higher user fee rates will be covered by higher APTC payments, which results in transferring funds from one program to another program.

Response: HHS believes that these newly finalized 2022 user fee rates will

⁹² 86 FR 6138 at 6152.

⁹³ 86 FR 7793 (Feb. 2, 2021).

⁹⁴ 86 FR 6138 at 6152.

⁹⁵ <https://www.cms.gov/newsroom/press-releases/biden-harris-administration-quadruples-number-health-care-navigators-ahead-healthcaregov-open>.

⁹⁶ 86 FR 24141.

provide adequate funding for the full functioning of the Federal platform, and HHS does not need to further increase these rates at this time. HHS acknowledges that the user fee rates in this final rule are higher than those previously finalized for 2022 in part 1 of the 2022 Payment Notice final rule, which could increase premiums for consumers, but in accordance with E.O. 12866, HHS believes that the benefits of this regulatory action justify the costs. The FFE and SBE-FP user fee rates for the 2022 benefit year are based on expected total costs to offer the special benefits to issuers offering plans on FFEs or SBE-FPs and were developed based on an evaluation of expected enrollment and premiums for the 2022 benefit year. HHS also notes that the 2022 user fee rates are still lower than the 2021 user fee rates.

Regardless, HHS 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. This will include annually evaluating outreach and education efforts to consider what the appropriate level of funding should be.

HHS also notes that it is consistent with the ACA and implementing regulations for user fees to be included in premiums (as determined by the issuer) and for these premiums to be partially covered by APTC payments for eligible enrollees.

Comment: Some commenters requested that HHS provide greater budget transparency and more data reporting on how and where user fees are spent.

Response: HHS believes that the information provided in the proposed rule in support of the proposed user fee rate was sufficient to allow commenters to meaningfully assess and comment on the appropriateness of the user fee rate proposals. The FFE and SBE-FP user fee rates for the 2022 benefit year are based on expected total costs to offer the special benefits to issuers offering plans on FFEs or SBE-FPs, and are based on an evaluation of expected enrollment and premiums for the 2022 benefit year. Annually, HHS and CMS also publish detailed information on Federal Exchange Activities and budget request estimates, including expected Exchange user fee-eligible costs.⁹⁷ To calculate these expected costs, HHS makes reasonable assumptions about the

expected market for the upcoming benefit year, and reconsiders these assumptions and re-estimate these costs on an annual basis with the most recent data available. For example, for the 2022 benefit year, HHS considered whether they needed to make changes to the cost, premium, and enrollment assumptions based on data from the 2020 benefit year and made updates to their projections as appropriate. User fee-eligible costs are generally estimated in advance of the benefit year and are based upon cost targets for specific contracting activities that are not yet finalized, and therefore contain proprietary information related to contracting activities that should not be disclosed. HHS will continue to outline user fee-eligible functional areas in the annual HHS notice of benefit and payment parameters, and will evaluate contract activities related to operation of Federal platform user fee-eligible functions.

Comment: HHS received comments that HHS should switch to a per member per month (PMPM) capitated user fee, rather than a premium based user fee, and a comment requesting that HHS conduct and publish a study on a PMPM user fee.

Response: HHS did not propose to switch to a PMPM capitated user fee and therefore is not finalizing a PMPM capitated user fee. The FFE and SBE-FP user fee rates will continue to be assessed as a percent of the monthly premium charged by participating issuers. Setting the user fee as a percent of premium avoids disproportionately increasing premiums in lower-cost areas and for lower-premium plans, since, holding all other factors constant, issuers of plans with lower premiums will experience lower user fees, and issuers of plans with higher premiums will experience a proportional increase in user fees. Although a PMPM user fee rate would yield lower user fees for higher-premium plans, it would likely cause issuers of lower-premium plans to increase premiums, thus decreasing the affordability of the most affordable plans.

Comment: One commenter suggested that more user fee money be aimed at enrolling immigrants by, for example, offering the option to receive educational material in different languages.

Response: A portion of user fee funds is used for the management of the FFE Navigator program, as well as consumer outreach and education for the FFEs and SBE-FPs. In previous Payment Notices, commenters have acknowledged the important role that Navigators play in assisting individuals with LEP. On

August 27, 2021, CMS awarded \$80 million in grant funding to 60 Navigator grantees in 30 states with an FFE for the 2022 plan year.⁹⁸ This is the largest funding allocation HHS has made available for Navigator grants to date. As part of this grant funding, HHS has encouraged current and past Navigators to apply, especially those that focus on education, outreach, and enrollment efforts to underserved and diverse communities, including those with LEP. HHS also notes that under § 155.205(c)(2)(i)(A), HHS currently provides accessibility services in at least 150 languages at no cost to applicants and enrollees. These translation services are provided telephonically and for written communications at no cost to the consumer.

After considering the public comments, HHS is finalizing the proposed rates of 2.75 percent for the FFE user fee rate and 2.25 percent for the SBE-FP user fee rate for the 2022 benefit year.

c. 2023 Exchange DE Option User Fee Rate

In the January 19, 2021 **Federal Register** (86 FR 6138), HHS published part 1 of the 2022 Payment Notice final rule that codified § 155.221(j), which established a process for states to elect a new Exchange DE option. When finalizing this new Exchange option, HHS also finalized a 2023 user fee rate of 1.5 percent of the total monthly premiums charged by issuers for each policy in FFE and SBE-FP states that elect the Exchange DE option. As explained earlier in this preamble, HHS proposed to repeal the Exchange DE option; accordingly, HHS also proposed to repeal the user fee rate associated with § 155.221(j) for the FFE-DE and SBE-FP-DEs for 2023. HHS sought comment on this proposal.

HHS did not receive public comments specific to the proposal to repeal the user fee rates for FFE-DEs and SBE-FP-DEs for 2023. HHS summarizes the comments received on the accompanying proposal to repeal the Exchange DE option under part 155 earlier in this preamble. After consideration of those comments, HHS is finalizing the proposal to repeal the Exchange DE option and the accompanying 2023 user fee rates for FFE-DEs and SBE-FP-DEs, as proposed.

⁹⁷ The FY 2022 CMS Budget Request is available at <https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf> and the FY 2022 HHS Budget Request is available at <https://www.hhs.gov/sites/default/files/fy-2022-budget-in-brief.pdf>.

⁹⁸ <https://www.cms.gov/newsroom/press-releases/cms-announces-80-million-funding-opportunity-available-navigators-states-federally-facilitated-0>
<https://www.cms.gov/newsroom/press-releases/biden-harris-administration-quadruples-number-health-care-navigators-ahead-healthcaregov-open>.

2. Provision of EHB (§ 156.115)

HHS proposed a technical amendment to § 156.115. Section 156.115(a)(3) provides that, to satisfy the requirement to provide EHB, a health plan must provide mental health and substance use disorder services, including behavioral health treatment services required under § 156.110(a)(5), in a manner that complies with the parity standards set forth in § 146.136, implementing the requirements under MHPAEA. Instead of referencing the regulation implementing MHPAEA, HHS proposed to reference section 2726 of the PHS Act and its implementing regulations. HHS proposed this change to make clear that health plans must comply with all the requirements under MHPAEA, including any amendments to MHPAEA, such as those made by the Consolidated Appropriations Act, 2021,⁹⁹ in order to satisfy the EHB requirements.

The following is a summary of the comments received and responses to the HHS proposals related to EHB provision (§ 156.115).

Comment: HHS received several comments in support of the proposed amendment. The commenters expressed that the amendment would affirm HHS' commitment to the goal of ensuring access to mental health and substance use disorder coverage for individuals, and also will strengthen national and local efforts to enforce MHPAEA requirements.

Response: HHS appreciates the support of the commenters and are finalizing this policy as proposed.

3. Network Adequacy (§ 156.230)

As discussed in more detail in the preamble to § 155.20, on March 4, 2021, the United States District Court for the District of Maryland decided *City of Columbus v. Cochran*, 2021 WL 825973 (D. Md. Mar. 4, 2021). One of the policies the court vacated was the 2019 Payment Notice's elimination of the Federal Government's reviews of the network adequacy of QHPs offered through the FFEs in certain circumstances by incorporating the results of the states' reviews.¹⁰⁰

As explained in part 2 of the 2022 Payment Notice final rule,¹⁰¹ HHS intends to implement the court's decision through rulemaking as soon as possible. However, HHS also will not be able to fully implement the aspects of the court's decision regarding network adequacy in time for issuers to design plans and for CMS to be prepared to certify such plans as QHPs for the 2022 plan year. HHS noted in the proposed rule that HHS instead intends to address these issues in time for plan design and certification for plan year 2023. Specifically, with the rule vacated, HHS would need to set up a new network adequacy review process, and issuers would need sufficient time before the applicable plan year to assess that their networks meet the new regulatory standard, submit network information, and have the information reviewed by applicable regulatory authorities to have their plans certified as QHPs. Issuers might also have to contract with other providers in order to meet the standard. This was not feasible for the QHP certification cycle for the 2022 plan year, which began on April 22, 2021. HHS plans to propose specific steps to address Federal network adequacy reviews in future rulemaking. HHS requested comments and input regarding how the Federal Government should approach network adequacy reviews.

The following is a summary of the comments received and the responses to HHS' solicitation for comments related to network adequacy (§ 156.230).

Comment: Many commenters highlighted the importance of ensuring adequate network access for all consumers seeking coverage through QHPs offered through the FFEs. Commenters encouraged HHS to specifically review networks for: full accessibility to consumers with disabilities, language access, cultural competency, capacity to deliver anti-bias care, specialist and sub-specialist access, end-of-life care services, diverse providers reflecting backgrounds of enrollees, and extended hours of operation. Commenters also suggested networks' capacity to deliver LGBTQ+-affirming care should be assessed as part of network adequacy review processes. Other commenters specified that broad and equitable access to sexual and reproductive health services, contraceptive services, and HIV care should be evaluated.

Response: HHS agrees that adequacy metrics supporting equitable access for all consumers should be a high priority. For future rulemaking, HHS is carefully

considering standards that promote health equity (for example, provider directory requirements to include information about the race/ethnicity, language(s) spoken, accessibility, and office hours of in-network providers).

Comment: Many commenters offered network adequacy enforcement strategies for HHS to consider, stating HHS should implement direct testing of provider availability as an enforcement method, per the 2014 HHS Office of Inspector General Report.¹⁰² Others encouraged HHS to examine out-of-network claims submission rates and claims denials rates (adjusted for enrollment numbers) to monitor and enforce network adequacy. Additional enforcement and monitoring strategies cited by commenters included: submission and review of access plans for new networks, submission and review of parity compliance reports on network standards, use of consumer surveys and complaint data, and use of geographic mapping tools and secret shopper surveys to identify adequacy gaps.

Response: HHS will take these comments under advisement when detailing the specific criteria and processes for meeting network adequacy standards.

Comment: Some comments cautioned against creating a quantitative Federal standard that is overly prescriptive for issuers, citing differences across states. A Federal standard may not allow for the needed tailored flexibilities and innovations in adequacy assessment that respond to the unique workforces, geographies, populations, and markets of each state. Additionally, several comments called for maximum consistency of approach across states. One commenter encouraged HHS to utilize the network adequacy standards developed by the National Committee for Quality Assurance (NCQA) for medical and behavioral health services. Conversely, one commenter noted accreditation organizations are not the appropriate arbiter of network adequacy.

Response: HHS aims to establish Federal oversight standards that complement state standards while meeting Federal obligations, including for QHPs on FFEs. HHS will continue to coordinate closely with state authorities to address compliance issues, eliminate duplicative requirements or reviews, and reduce stakeholder burden.

Comment: Several comments supported the application of telehealth for fulfilling network adequacy

⁹⁹ See section 203 of Title II of Division BB of the Consolidated Appropriations Act, 2021, Public Law 116-260 (Dec. 27, 2020).

¹⁰⁰ This policy was first announced in the 2018 Letter to Issuers in the federally-facilitated Marketplaces, December 16, 2016, available at <https://wayback.archive-it.org/2744/20200125161008/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>. See also 83 FR 17024-17026.

¹⁰¹ 86 FR 24140.

¹⁰² <https://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf>.

standards. Some commenters cautioned against the use of telehealth or virtual-only providers to fulfill quantitative standards for adequacy in lieu of in-person care.

Response: Telehealth is of special interest to HHS given its recent expansion during the COVID-19 pandemic. HHS intends to detail the specific criteria and processes for meeting network adequacy standards. Standards that account for the availability of telehealth services are under consideration.

Comment: Some commenters asserted that Federal network adequacy reviews should prevent discrimination against and examine the availability of a diverse set of provider types, including nurse practitioners, certified registered nurse anesthetists, and other mid-level practitioners. Commenters called for including all applicable provider types such as skilled nursing facilities, durable medical equipment suppliers, and prosthetists and orthotists. Specifically, some commenters noted the importance of ensuring access, via quantitative standards, to behavioral health and substance use disorder providers and services at all care levels, including intermediate care.

Response: HHS intends to evaluate QHP issuer networks for access to providers enrollees most generally use and/or that have historically been the subject of network adequacy concerns raised by patients and other stakeholders (for example, behavioral health providers).

Comment: Commenters suggested use of a range of general and specific network adequacy metrics and standards, including time and distance, provider-to-enrollee ratio minimums, availability of providers accepting new patients, timely notification of provider terminations, provision of out-of-network services, provider directory data elements, and appointment wait times. Commenters also suggested that when assessing network adequacy, HHS should consider enrollees' health care needs (for example, by using the Community Need Index) and transportation and topographical complexities that influence geographic accessibility.

Response: HHS intends to ensure that network adequacy standards ensure enrollee access to care, are applicable and meaningful across diverse state settings, are achievable, and do not place an undue burden on issuers to collect and validate the necessary data.

HHS will take the comments into consideration while formulating forthcoming rulemaking. HHS will also consider these comments in specifying

QHP certification requirements related to network adequacy. Pursuant to 45 CFR 156.230(a)(2), an issuer of a QHP that has a provider network must maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to assure that all services will be accessible to enrollees without unreasonable delay.

For the certification cycle for plan years beginning in 2023, HHS is considering the adoption of time and distance standards to assess whether QHP issuer networks fulfill this regulatory requirement. HHS is considering evaluating QHP issuer networks for compliance with this standard based on the numbers and types of providers that enrollees most generally use and/or that have historically been the subject of network adequacy concerns raised by patients and other stakeholders (for example, behavioral health providers); providers' geographic location; and other factors to be determined by HHS. HHS would calculate time and distance standards at the county level. Issuers that are unable to meet the specified standards would be able to submit a justification to account for variances, and the FFEs would review the justification to determine whether the variance(s) is/are reasonable based on a specific set of circumstances, such as the local availability of providers and variables reflected in local patterns of care. HHS would also include a requirement for issuers to make the information necessary to evaluate their QHP issuer networks under these standards available in a machine-readable file and format specified by HHS.

HHS anticipates:

- Using standards that are informed by those used in Medicare Advantage;
- Implementing methodologies that account for local geographical and topographical features that influence real-world access to providers such as the physical environment (for example, bodies of water, unpassable mountainous areas) and varied travel modes (for example, car, public transportation); and
- Expanding the use of the JavaScript Object Notation (JSON) files QHP issuers currently make available as part of meeting provider directory requirements.

In light of the expanded use of, and reimbursement for, telehealth services during the COVID-19 PHE, time and distance standard methodologies that account for the availability of telehealth services are also under consideration.

For future rulemaking, HHS is carefully considering other network adequacy standards, including appointment wait times and standards that promote health equity (for example, provider directory requirements to include information about the race/ethnicity, language(s) spoken, accessibility, and office hours of in-network providers).

4. Segregation of Funds for Abortion Services (§ 156.280)

HHS proposed to repeal the separate billing regulation at § 156.280(e)(2)(ii) that required individual market QHP issuers to send a separate bill for that portion of a policy holder's premium that is attributable to coverage for abortion services for which Federal funds are prohibited and to instruct such policy holders to pay for the separate bill in a separate transaction. Specifically, HHS proposed to revert to and codify in amended regulatory text at § 156.280(e)(2)(ii) the prior policy announced in the preamble of the 2016 Payment Notice under which QHP issuers offering coverage of abortion services for which Federal funds are prohibited have flexibility in selecting a method to comply with the separate payment requirement in section 1303 of the ACA. As proposed, HHS noted that individual market QHP issuers covering such abortion services would still be expected to comply with all statutory requirements in section 1303 of the ACA and all applicable regulatory requirements codified at § 156.280. HHS is finalizing removal of the separate billing regulation and codification of the prior policy at § 156.280(e)(2)(ii) as proposed.

Section 1303 of the ACA outlines requirements that issuers of individual market QHPs covering abortion services for which Federal funds are prohibited must follow to ensure compliance with these funding limitations, which are based on the law in effect as of the date that is 6 months before the beginning of the plan year involved. Since 1976, Congress has included language, commonly known as the Hyde Amendment, in the Labor, Health and Human Services, Education and Related Agencies appropriations legislation that sets out funding restrictions for abortions.¹⁰³ The Hyde Amendment, as currently in effect, permits Federal funds subject to its funding limitations to be used for abortion services only in the limited cases of rape, incest, or if a

¹⁰³ The Hyde Amendment is not permanent Federal law, but applies only to the extent reenacted by Congress from time to time in appropriations legislation.

woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed. Abortion coverage beyond those limited circumstances is subject to the Hyde Amendment's funding limitations which prohibit the use of Federal funds for such coverage.

Section 1303(b)(2) prohibits QHPs from using any amount attributable to PTC (including APTC) or CSRs (including advance payments of those funds to an issuer, if any) for coverage of abortion services for which Federal funds are prohibited. Under sections 1303(b)(2)(B) and (b)(2)(D) of the ACA, as implemented in § 156.280(e)(2)(i) and (e)(4), QHP issuers must collect a separate payment from each enrollee without regard to the enrollee's age, sex, or family status, for an amount equal to the greater of the AV of coverage of abortion services for which public funding is prohibited, or \$1 per enrollee per month. Section 1303(b)(2)(D) of the ACA establishes certain requirements with respect to a QHP issuer's estimation of the AV of abortion services for which Federal funds are prohibited including that a QHP issuer may not estimate such cost at less than \$1 per enrollee, per month. Section 1303(b)(2)(C) of the ACA, as implemented at § 156.280(e)(3), requires that QHP issuers segregate funds for coverage of such abortion services collected from enrollees into a separate allocation account used to pay for such abortion services. Thus, if a QHP issuer disburses funds for an abortion for which Federal funds are prohibited on behalf of an enrollee, it must draw those funds from the segregated allocation account.

Notably, section 1303 of the ACA does not specify the method a QHP issuer must use to comply with the separate payment requirement under section 1303(b)(2)(B)(i) of the ACA. In the 2016 Payment Notice, HHS provided guidance with respect to acceptable methods that an issuer of individual market QHPs could use to comply with the separate payment requirement.¹⁰⁴ HHS stated that QHP issuers could satisfy the separate payment requirement in one of several ways, including by sending the enrollee a single monthly invoice or bill that separately itemized the premium amount for coverage of abortion services for which Federal funds are prohibited; sending the enrollee a separate monthly

bill for these services; or sending the enrollee a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge. HHS also stated that an enrollee could make the payment for coverage of such abortion services and the separate payment for coverage of all other services in a single transaction.¹⁰⁵ On October 6, 2017, HHS released a bulletin that discussed the statutory requirements for separate payment, as well as this previous guidance on the separate payment requirement.¹⁰⁶

The 2019 Program Integrity Rule¹⁰⁷ prohibited the compliance options that the 2016 Payment Notice previously provided to QHP issuers with regard to the separate payment requirement. Specifically, the 2019 Program Integrity Rule finalized a policy requiring issuers of individual market QHPs offering coverage of abortion services for which Federal funds are prohibited to send an entirely separate monthly bill to policy holders just for the portion of the premium attributable to coverage of such abortion services. QHP issuers were required to either send separate paper bills (which could be sent in the same envelope or mailing), or send separate bills electronically (which were required to be in separate emails or electronic communications). The separate billing regulation also required QHP issuers to instruct the policy holder to pay for the portion of their premium attributable to coverage of abortion services for which Federal funds are prohibited through a separate transaction from any payment made for the portion of their premium not attributable to this coverage. It also required QHP issuers to make reasonable efforts to collect the payments separately. QHP issuers were to begin complying with these billing requirements on or before the QHP issuer's first billing cycle following June 27, 2020. Although HHS recognized that the previous methods of itemizing or providing advance notice about the amounts noted as permissible in the preamble of the 2016 Payment Notice arguably identified two 'separate' amounts for two separate purposes, HHS also reasoned that the separate billing policy would better align the regulatory requirements for QHP issuer billing of enrollee premiums with the

intent of the separate payment requirement in section 1303 of the ACA.¹⁰⁸

HHS announced in the 2019 Program Integrity Rule that it would exercise enforcement discretion to mitigate risk of inadvertent coverage terminations that might result from enrollee confusion in connection with receiving two separate bills for one insurance contract. HHS explained that it would not take enforcement action against a QHP issuer that implemented a policy under which the issuer would not place an enrollee into a grace period and would not terminate QHP coverage based solely on the policy holder's failure to pay the separate bill. The 2019 Program Integrity Rule provided that HHS was adopting this enforcement posture effective June 27, 2020.

In response to the proposal to adopt the separate billing requirement finalized in the 2019 Program Integrity Rule, HHS also received comments expressing concern that lack of transparency into whether QHPs provided coverage of abortion services for which Federal funds are prohibited presented the risk that consumers could unknowingly purchase such coverage. To address this risk, HHS announced that as of the effective date of the final rule, February 25, 2020, it would not take enforcement action against QHP issuers that allowed enrollees to opt out of coverage of such abortion services by not paying the separate bill for such services (the opt-out non-enforcement policy). The opt-out non-enforcement policy effectively gave issuers the flexibility to modify the benefits of a plan during a plan year based on an enrollee's desire to opt out of a plan's coverage of such abortion services.

In light of the immediate need for QHP issuers to divert resources to respond to the COVID-19 PHE, HHS published an interim final rule with comment in May 2020 for Medicare and Medicaid Programs, Basic Health Programs and Exchanges ("May 2020 IFC").¹⁰⁹ Finalized at § 156.280(e)(2)(ii), the rule delayed by 60 days the date when individual market QHP issuers would be required to begin separately billing policy holders such that QHP issuers were expected to comply with the separate billing regulation beginning on or before the QHP issuer's first billing cycle following August 26, 2020. The May 2020 IFC noted that a 60-day delay was justified in light of the ongoing litigation in Federal courts in Maryland, Washington, and California challenging the separate billing

¹⁰⁵ 80 FR 10750, 10840 (February 27, 2015).

¹⁰⁶ CMS Bulletin Addressing Enforcement of Section 1303 of the Patient Protection and Affordable Care Act (October 6, 2017), available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Section-1303-Bulletin-10-6-2017-FINAL-508.pdf>.

¹⁰⁷ 84 FR 71674 (December 27, 2019).

¹⁰⁸ 84 FR 71674, 71693.

¹⁰⁹ 85 FR 27550.

¹⁰⁴ 80 FR 10750 (February 27, 2015).

regulation. The May 2020 IFC also noted that the extended compliance deadline would only apply to the non-enforcement policy under which issuers would have flexibility to refrain from triggering grace periods or coverage terminations where a policy holder failed to pay the separate monthly bill, delaying when this enforcement posture would become available by 60 days (to August 26, 2020).

A district court in Washington¹¹⁰ invalidated the 2019 Program Integrity Rule's separate billing regulation in the state of Washington in April 2020, and district courts in Maryland¹¹¹ and California¹¹² vacated the 2019 Program Integrity Rule's separate billing regulation in July 2020, in advance of the postponed compliance deadline of August 26, 2020. On April 9, 2020, the United States District Court for the Eastern District of Washington issued an opinion declaring the separate billing regulation invalid in the State of Washington.¹¹³ The district court specifically found that the separate billing regulation was in conflict with Washington's "Single-Invoice Statute,"¹¹⁴ which requires health insurance issuers in the state to bill enrollees using a single invoice. The district court held that the separate billing regulation did not preempt Washington's Single-Invoice Statute.

On July 10, 2020, the United States District Court for the District of Maryland found the separate billing regulation to be contrary to section 1554 of the ACA and arbitrary and capricious under the Administrative Procedure Act, thus declaring it invalid and unenforceable nationwide.¹¹⁵ The district court found the separate billing regulation to be in conflict with section 1554 of the ACA, which, among other key provisions, prohibits the Secretary from promulgating regulations that create any unreasonable barriers to obtaining appropriate medical care or impede timely access to health care services. The district court concluded that the policy imposed an unreasonable barrier because it would make it harder for enrollees to pay for insurance because they must keep track of two

separate bills, which is likely to cause confusion and might lead to some enrollees losing health insurance. The district court also held the separate billing regulation to be arbitrary and capricious, finding that HHS failed to provide a reasoned explanation for abandoning the policy that existed prior to the adoption of the current separate billing regulation in the 2019 Program Integrity Rule. The district court also held that the implementation deadline was arbitrary and capricious because HHS failed to consider and adequately address specific, contrary evidence from regulated stakeholders that the implementation deadline for compliance with the separate billing regulation was unreasonable and would not provide QHP issuers with sufficient time to comply.

On July 20, 2020, the United States District Court for the Northern District of California issued an opinion¹¹⁶ holding that the separate billing regulation was arbitrary and capricious, setting it aside nationwide. The district court held that the required mid-year implementation date for issuers to comply with the separate billing regulation would cause substantial transactional costs to states, issuers, and enrollees without any corresponding benefit. The court further found that the 2019 Program Integrity Rule lacked a reasoned explanation for deviating from the prior acceptable methods available to QHP issuers for compliance with the separate payment requirement and for departing from industry billing practice.

HHS initially appealed all three decisions, but those appeals have been placed on hold following the recent change in administration. As explained in the proposed rule, in light of these developments, and upon further consideration of the court decisions invalidating the policy, HHS reassessed the value of the separate billing regulation and no longer believe it is justified in light of the high burden it would impose on issuers, states, Exchanges, and consumers, as well as the high likelihood of consumer confusion and unintended losses of coverage. Nor does HHS believe section 1303 of the ACA restricts issuers offering coverage of abortion services for which Federal funds are prohibited to collect the required separate payment through a separate bill and instruct consumers to pay for such a bill in a separate transaction. Rather, section 1303 of the ACA outlines requirements that issuers of individual market QHPs

covering abortion services for which Federal funds are prohibited must follow to ensure that no public funding is utilized for coverage of such abortion services, including requiring issuers to collect separate payments for this portion of the premium, to segregate the funds, and to deposit such funds into separate allocation accounts. As the 2019 Program Integrity Rule acknowledged, section 1303 of the ACA does not specify the method a QHP issuer must use to comply with the separate payment requirement.¹¹⁷

After considering comments received on this proposal, HHS is finalizing amendments to § 156.280(e)(2)(ii) to revert to and codify the policy previously adopted in the 2016 Payment Notice such that QHP issuers offering coverage of abortion services for which Federal funds are prohibited have flexibility in selecting a reasonable method to comply with the section 1303 separate payment requirement. As finalized, acceptable methods for satisfying the separate payment requirement are outlined at § 156.280(e)(2)(ii) and include sending the policy holder a single monthly invoice or bill that separately itemizes the premium amount for coverage of such abortion services; sending the policy holder a separate monthly bill for these services; or sending the policy holder a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge. Since HHS is finalizing these policies, the non-enforcement policies adopted in the 2019 Program Integrity rule and the May 2020 IFC are discontinued.

HHS is also finalizing as proposed the technical change to the section heading of § 156.280 to more accurately reflect its contents. As finalized, it will instead read, "Segregation of funds for abortion services."

Comment: The majority of commenters supported the proposed changes to repeal the separate billing regulation and codify the prior policy at § 156.280(e)(2)(ii). A minority of commenters objected to the proposal.

Commenters supporting repeal of the separate billing regulation asserted that eliminating the separate billing requirements would streamline issuer billing practices, alleviate consumer and issuer burden, lessen the confusion for consumers pertaining to billing for their health needs, and prevent termination of coverage that would have otherwise resulted from substantial consumer confusion over a second bill for such a miniscule amount. These commenters

¹¹⁰ *Washington v. Azar*, 461 F. Supp. 3d 1016 (E.D. Wash. 2020).

¹¹¹ *Planned Parenthood of Maryland, Inc. v. Azar*, No. CV CCB-20-00361 (D. Md. July 10, 2020); 5 U.S.C. 706.

¹¹² *California v. U.S. Dep't of Health & Hum. Servs.*, 473 F. Supp. 3d 992 (N.D. Cal. July 20, 2020).

¹¹³ *Washington v. Azar*, 461 F. Supp. 3d 1016 (E.D. Wash. 2020).

¹¹⁴ Wash. Rev. Code § 48.43.074.

¹¹⁵ *Planned Parenthood of Maryland, Inc. v. Azar*, No. CV CCB-20-00361 (D. Md. July 10, 2020); 5 U.S.C. 706.

¹¹⁶ *California v. U.S. Dep't of Health & Hum. Servs.*, 473 F. Supp. 3d 992 (N.D. Cal. July 20, 2020).

¹¹⁷ 84 FR 71674, 71683.

highlighted how the separate billing regulation would have caused considerable and unnecessary confusion and frustration for consumers that may have jeopardized their health insurance coverage if not for court intervention invalidating the policy prior to implementation. Commenters supporting repeal also noted that the separate billing framework contradicted well established industry practices for sending one bill for the entire premium for a set period. These commenters highlighted that HHS never offered examples of where the new approach of separate billing is used for other types of insurance billing successfully and without harm to consumers, and that HHS broadly failed to support the change to separate billing with evidence that the approach was reasonable. Commenters stated that such an unreasonable requirement is arbitrary and capricious and therefore unlawful, and noted that the separate billing regulation was so egregious of an interpretation of section 1303 of the ACA that multiple Federal courts invalidated the policy in 2020.

Commenters supported repeal from both a policy and legal perspective, noting that repeal of the separate regulation aligns with the vacatur of the policy by multiple Federal district courts in 2020. Commenters specifically raised that the Maryland District Court vacated the separate billing regulation in part because it would have created unreasonable barriers to obtaining appropriate medical care and impeded timely access to health care services, as it would have made it harder for enrollees to pay for insurance by making consumers keep track of two separate bills—in conflict with section 1554 of the ACA. Commenters also noted that court decisions invalidating the separate billing regulation focused on the harm that the requirements would have caused to enrollees if it went into effect. For example, commenters emphasized that the United States District Court for the Northern District of California issued an opinion holding that the separate billing regulation was arbitrary and capricious and focused on the substantial costs of the policy to states, issuers, and enrollees without any corresponding benefit.

Commenters also raised that the separate billing regulation was incompatible with some state laws, including Washington law. Commenters asserted that the United States District Court for the Eastern District of Washington found that the separate billing regulation was invalid in Washington State because of Washington's "single invoice statute,"

which the court found was not preempted by the separate billing regulation.

Commenters also expressed support for codifying the policy put in place under the 2016 Payment Notice for issuer compliance with section 1303's separate payment requirement, asserting that separately billing was unnecessary to achieve the congressional objective to section 1303 of segregating funds into separate allocation accounts and ensuring no Federal funds are used for coverage of abortion services for which Federal funding is prohibited. Specifically, commenters noted that for the five years preceding the separate billing regulation, individual market QHP issuers covering abortion services for which Federal funding is prohibited had executed HHS-approved methods for complying with section 1303 as permitted under the 2016 Payment Notice and, in doing so, achieved the congressional intent of segregating funds as the statute requires, without the variety of negative consequences from the separate billing regulation. Supporting commenters explained that reverting to the pre-2019 policy properly prioritizes a more efficient policy that will alleviate any burden the separate billing regulation would have imposed on consumers and issuers. Commenters commended HHS for proposing to allow issuers and states to choose the best compliance option for the separate payment requirement in section 1303 that will minimize carrier and consumer burden in the context of the local, state-specific landscape.

Some commenters expressing strong support for repeal of the separate billing policy and codification of the prior policy also asserted that, because the separate billing regulation has been vacated and because issuers never implemented the requirements, HHS does not technically need to finalize the proposed rule in order to grant issuers, consumers, and other stakeholders the requisite relief. These commenters emphasized that, by virtue of the Federal district courts' vacatures, the policy finalized in the preamble of the 2016 payment notice is already currently in effect, which was itself a policy adopted after notice-and-comment rulemaking.

Other commenters supported the repeal of the separate billing regulation and codification of the pre-2019 policy, but requested that HHS prohibit issuers from sending separate bills entirely. These commenters asserted that compliance with section 1303 falls on the issuers, not the consumers, and that the negative consequences of the issuer billing and the consumer paying for

coverage through separate transactions—increasing consumer confusion without any real benefit and the risk of coverage termination—are significant. Commenters noted that section 1303 requires that any notice regarding payments "shall provide information only with respect to the total amount of the combined payments for services" covered by the plan and that this restriction suggests that bills regarding abortion should only bill "the total amount of the combined payments." These commenters therefore urged HHS to eliminate the option for QHP issuers to send a separate monthly bill for abortion services for which Federal funding is prohibited because it is prohibited by the statute, consistent with the purpose of section 1303, and supported by the record and common industry practice. Other commenters urged HHS to emphasize the third option for compliance, sending the consumer a notice at or shortly after time of enrollment, over the others as it is the least burdensome to consumers and would reduce potential confusion. If the option to send separate bills is maintained, some commenters encouraged HHS to consider adopting consumer protections to guard against the potential for policy holders to lose their health insurance coverage because they fail to pay the *de minimis* amount of the separate premium bill for abortion services for which Federal funds are prohibited, if issuers still choose to send separate bills.

Commenters opposing the proposal objected to abortion coverage altogether and asked that HHS retain the separate billing regulation and continue to require separate checks, separate envelopes, and separate transactions for all QHPs that provide coverage for abortion services for which Federal funding is prohibited. Many commenters objecting to the proposal also asked that HHS allow issuers to permit consumers to opt out of such coverage by refusing to pay the portion of their premium attributable to coverage for abortions for which Federal funding is prohibited. Objecting commenters also challenged the assertion that the separate billing regulation would cause undue consumer confusion, pointing to how some policy holders receive multiple bills anyway from their insurance issuers or providers, such as consumers who have Medicare as well as a supplemental Medigap policy.

Objecting commenters generally argued that section 1303 of the ACA expressly requires separate billing as the only appropriate method for collection of the separate payment required under

section 1303, that the burden estimated for implementation of the separate billing regulation is necessary to achieve compliance with the statute, and that repeal of the separate billing regulation will deprive consumers of needed transparency into coverage for which they may object on conscience or other grounds. Commenters asserted that all of the revised options for compliance with section 1303 proposed at § 156.280(e)(2)(ii) other than separate billing are inadequate to satisfy the section 1303 requirement as they would conceal the portion of the premium attributable to certain abortion services and would permit issuers to collect monthly premiums in a single, rather than separate, payment. Commenters also questioned HHS's reasoning for continuing to allow issuers to bill separately as one of the available compliance options when such a billing method leads to so many unjustified burdens, consumer confusion, barriers to care, and inequities.

Most commenters supported the proposal to change the section heading of § 156.280 to "Segregation of funds for abortion services." Commenters asserted that this technical change would better align with the intention of section 1303 of the ACA which expressly requires issuers to segregate funds and accounts for certain abortion coverage but does not pass on that burden to consumers. Commenters that objected to the proposal to repeal the separate billing regulation also objected to renaming the section heading, arguing that the technical change is inappropriate and a further attempt to establish regulations that deviate from the law, for the same reasons that such commenters object to the proposal overall.

Response: HHS agrees with commenters that repealing the separate billing regulation is consistent with the Federal district court decisions invalidating the separate billing regulation and the requirements of section 1303 of the ACA. HHS also agrees that codifying the pre-2019 policy reinstates a policy that supports meaningful issuer compliance with section 1303 by ensuring appropriate segregation of funds as required by statute, without imposing the operational and administrative burdens of the separate billing regulation and without causing additional consumer confusion and unintended losses of coverage.

Although HHS acknowledges that some commenters continue to support the separate billing regulation, HHS emphasizes that multiple Federal district courts have already invalidated the separate billing regulation,

preventing HHS from requiring its implementation.

HHS agrees with commenters' assertions that the invalidation of the separate billing regulation by the Federal district courts is binding on HHS and currently prohibits implementation of the separate billing policy.¹¹⁸ HHS also believes the potential harms to consumers, costs to issuers and states, consumer confusion, and potential loss of consumer coverage that would have occurred under the separate billing regulation warrant a formal repeal of the policy through notice and comment rulemaking not only to reflect these legal developments but also to rectify the interpretation and implementation of section 1303 of the ACA as a matter of Federal policy. HHS also believes it is important to codify the pre-2019 options for issuer compliance with section 1303 of the ACA, as such compliance options were noted only in the preamble to the 2016 Payment Notice. Taken together, HHS believes the Federal district court cases invalidating the separate billing regulation in combination with finalizing repeal of the regulation and codifying the pre-2019 options in this rule will provide additional clarity regarding compliance with section 1303 for stakeholders and remove contradictory policy interpretations at the Federal level.

Therefore, HHS is repealing the separate billing regulation and codifying the policy previously adopted in the 2016 Payment Notice such that QHP issuers offering coverage of abortion services for which Federal funds are prohibited again have flexibility in selecting a reasonable method to comply with the section 1303 separate payment requirement. As finalized at § 156.280(e)(2)(ii), acceptable methods for satisfying the separate payment requirement include sending the policy holder a single monthly invoice or bill that separately itemizes the premium amount for coverage of such abortion services; sending the policy holder a separate monthly bill for these services; or sending the policy holder a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge. As finalized, issuers will no longer be required to send separate paper bills or separate electronic communications for the portion of the policy holder's premium

attributable to coverage of abortions services for which Federal funding is prohibited. Nor will an issuer electing to send separate bills, or utilizing any of the acceptable methods for collecting the separate payment, be required to instruct consumers to pay for the portion of their premium attributable to coverage of abortion services for which Federal funds are prohibited in a separate transaction, or to make efforts to collect these payments separately.

HHS again emphasizes that under this finalized revision to § 156.280(e)(2)(ii), individual market QHP issuers covering abortion services for which Federal funds are prohibited are still required to comply with section 1303 of the ACA and all applicable requirements codified at § 156.280. As discussed in the proposed rule, this includes collecting a separate payment from each policy holder per month for an amount equal to the greater of \$1 or the AV of coverage of abortion services for which Federal funds are prohibited, continuing to ensure that no Federal funding is used to pay for coverage of such abortion services, submitting a plan to the relevant state insurance regulator outlining how it will comply with the segregation of funds requirements, and continuing to segregate funds for coverage of such abortion services collected from policy holders into a separate allocation account that is to be used to pay for such abortion services.

HHS understands commenter concerns regarding issuers that might choose to continue sending separate bills for the portion of the policy holder's premium attributable to abortion services for which Federal funding is prohibited. However, HHS continues to anticipate most issuers will decline to send two separate monthly bills and will instead choose to collect separate payments by one of the other proposed acceptable methods, as those alternatives minimize administrative complexity for issuers, align with industry billing practice, are less costly and administratively burdensome, and promote a more seamless consumer billing and payment experience. Although sending two bills would continue to be an option under the revisions HHS is finalizing, HHS emphasizes that any issuer electing to send two separate monthly bills should do so in a manner that minimizes consumer confusion, promotes continuity of coverage, and complies with section 1303 of the ACA. For example, if an issuer still chooses to send two separate monthly bills, issuers should include both bills in the same mailing, include the total premium due on both bills, explain on both bills that

¹¹⁸ *Planned Parenthood of Maryland, Inc. v. Azar*, No. CV CCB-20-00361 (D. Md. July 10, 2020); 5 U.S.C. 706; *California v. U.S. Dep't of Health & Hum. Servs.*, 473 F. Supp. 3d 992 (N.D. Cal. July 20, 2020); *Washington v. Azar*, 461 F. Supp. 3d 1016 (E.D. Wash. 2020).

the total premium due is inclusive of the amount attributable to coverage of such abortion services for which Federal funding is prohibited, and explain that the consumer may pay for both bills in a single transaction. Issuers that do choose to send separate bills should also explain to the consumer that non-payment of any premium due, including for the portion of premium attributable to such abortion services, would continue to be subject to state and Federal rules regarding grace periods to mitigate risk of inadvertent loss of coverage from failure to pay a portion of the premium due. Although HHS encourages issuers to utilize the other available options for compliance, HHS also believes separately billing in the manner described (without direction to pay in two separate transactions and with adequate consumer protections in place) would comply with section 1303, which does not specify a single method for compliance with the separate payment requirement, and would continue to alleviate the burden from the rigid requirements of the separate billing regulation.

Comment: Commenters who objected to repealing the separate billing regulation argued that the revised options for compliance with section 1303's separate payment requirement would not adequately address the concerns of consumers who object to coverage of abortions for which Federal funding is prohibited based on their conscience or religion. Such commenters maintain that abortion is immoral, has no place in health care, and that the separate billing regulation is the best way to affirm consumer conscience rights. These commenters asserted that the proposed revisions to § 156.280(e)(2)(ii) weaken statutory prohibitions on Federal funding for certain abortions that protect the conscience rights of taxpayers consistent with the Hyde Amendment. Such commenters asked that HHS allow consumers to opt out of coverage for abortions for which Federal funding is prohibited by not paying the portion of their premium attributable to such coverage, thereby avoiding the separate charge entirely.

Objecting commenters also stated that repealing the separate billing regulation removes transparency for consumers into which QHPs cover abortion services for which Federal funding prohibited and that the proposal to codify prior policy options for compliance with section 1303 would leave it up to QHP issuer discretion to determine how to comply with the statutory requirements of the ACA, when in fact the only method that

complies with the statute existed under the separate billing regulation. Such commenters also asserted that the prior methods for compliance with section 1303 under the 2016 Payment Notice deprive consumers of needed transparency and allow many unwittingly to purchase plans that include abortion coverage that might be contrary to their religious and moral convictions. These commenters urged HHS to pursue greater transparency by being open to consumers about their coverage options and what they are paying for in their insurance.

Commenters supporting the proposal to repeal the separate billing regulation and codify the prior options for compliance noted that transparency on *HealthCare.gov* could be further improved for consumers who value coverage of abortion services by including language during plan selection that indicates when a plan does not cover abortion services for which Federal funding is prohibited so that consumers are aware of this lack of coverage and can seek out a different plan with such coverage.

Commenters supporting repeal also supported discontinuing the opt-out non-enforcement policy. These commenters noted that HHS never sought public comment on that policy, which was especially harmful to consumers as the opt-out would have applied not only to the policy holder but also to anyone else on the policy, such as a spouse or an adult child, potentially causing consumers to lose coverage of abortion services. Commenters supporting discontinuation of the opt-out non-enforcement policy also asserted that allowing opt-outs in this manner runs afoul of the plain language of section 1303, which distinguishes between plans that offer abortion coverage for which Federal funding is prohibited to all enrollees on one hand, and plans that do not offer such coverage, on the other. Commenters asserted that section 1303 therefore leaves no room for the issuer of a single plan to offer such abortion coverage to some enrollees but not others, or to permit enrollees to opt-out of such coverage and effectively turn a single plan otherwise approved by the Exchange and offered to consumers into two separate plans. Commenters also noted that, in announcing the opt-out non-enforcement policy, HHS did not quantify the financial impact that was certain to result from it, as the issuers and plan participants who maintained abortion coverage would be left to shoulder the cost of that coverage without those who had opted out.

Response: Repealing the separate billing regulation and codifying the prior policy will allow issuers to bill using one of the prior acceptable methods that would eliminate all risk of inadvertent coverage terminations that could result from consumer confusion due to receiving two monthly bills (one for a miniscule amount, not less than \$1) in connection with one insurance policy.

As such, HHS affirms that repealing the separate billing regulation will also discontinue the non-enforcement policies adopted in the 2019 Program Integrity Rule and the May 2020 IFC, including the opt-out non-enforcement policy, which were in large part intended to mitigate potential coverage losses resulting from enrollee confusion that leads to enrollees' failures to pay the separate, small monthly bill covering abortion services for which Federal funds are prohibited.

HHS acknowledges that the 2019 Program Integrity Rule noted that the opt-out non-enforcement policy was also intended to address commenter concerns regarding insufficient transparency into whether QHPs include coverage of abortion services for which Federal funds are prohibited and the risk that consumers could unknowingly purchase QHPs that include such coverage, and potentially conflict with their conscience. In response to comments again raising these concerns, HHS reiterates that it has already taken steps to improve transparency regarding QHP offerings of abortion coverage by making it easier for consumers to select QHPs that they believe are best suited to their needs and preferences. For instance, information is available during plan selection on *HealthCare.gov* that can assist consumers in more readily identifying QHPs that offer coverage of such abortion services and provide consumers with the requisite information to make an informed choice about their plan selections regarding coverage of such services.¹¹⁹ Further, although section 1303 requires collection of a separate payment and segregation of funds for coverage of certain abortion services, it does not require issuers to alert consumers to this coverage for purposes of transparency of benefits. Like with coverage of other benefits, consumers seeking a QHP that

¹¹⁹ Frequently Asked Questions for Agents, Brokers, and Assistants Providing Consumers with Details on Plan Coverage of Certain Abortion Services (November 21, 2018), available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-on-Providing-Consumers-with-Details-on-Plan-Coverage-of-Certain-Abortion-Services.pdf>.

covers abortion services should review plan details and plan documents for information during plan selection that affirms the plan's coverage of such services. Consumers are able to make plan selections based on their unique health needs and benefit coverage preferences prior to enrollment, and updates made to plan selection on *HealthCare.gov* to list coverage of abortion services for which Federal funding is prohibited facilitates this selection process for individuals with conscience objections or other preferences regarding their coverage.

Although HHS acknowledges that there are some states where there may be no QHP available on the Exchange that omits coverage for such abortion services, HHS again emphasizes that such plan availability is subject to state law and issuer choice in plan design as permitted under section 1303 of the ACA. Specifically, section 1303(b)(1)(A)(ii) specifies that an issuer shall determine whether or not the plan provides coverage for abortion services for which Federal funds are prohibited for the applicable plan year, expressly providing that issuers are able to determine whether to offer coverage for such abortion services, subject to state law. Therefore, it is state law that dictates to what extent issuers may cover abortion services for which Federal funding is prohibited, the issuer's option whether to offer such services pursuant to state law, and the enrollee's option whether to enroll in such a plan.

HHS therefore continues to believe that allowing an opt-out policy would conflict with the flexibility in issuer plan design expressly provided under section 1303. HHS also believes the opt-out non-enforcement policy conflicts with § 147.106(e)(1), which generally provides that only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan or an individual, as applicable.

It also specifies that any such modification in the individual market must be consistent with state law and be effective uniformly for all individuals with that product. Finally, the United States District Court for the Northern District of California cited the opt-out non-enforcement policy in finding that the 2019 Program Integrity Rule lacked a reasoned explanation for deviating from the prior acceptable methods available to QHP issuers for compliance with the separate payment requirement.¹²⁰ The court explained

that inclusion of the opt-out non-enforcement policy, which was not subject to public comment, supported the court's conclusion that HHS changed its prior policy without affording any reasoned explanation for the change.

For these reasons, and given that the separate billing requirements finalized in the 2019 Program Integrity Rule have been invalidated, these non-enforcement policies are no longer necessary or feasible long-term and are therefore discontinued. Section 1303 of the ACA requires certain billing, accounting, and notice requirements of issuers in the individual market to ensure that issuers that do offer abortion services for which Federal funding is prohibited do so in a manner that ensures separation of funds consistent with statute. HHS believes the permissible methods finalized at § 156.280(e)(2)(ii) for issuer compliance with section 1303 of the ACA offer issuers several ways to comply with section 1303 of the ACA in a manner that works best for them and minimizes burden on consumers.

Comment: Commenters supporting the proposal to repeal the separate billing regulation and codify the prior policy explained that the separate billing regulation would have imposed new overly burdensome costs on issuers, states, State Exchanges, and FFEs, which would have been passed on to consumers in the form of higher premiums.

Supporting commenters stated that issuers subject to the separate billing requirements would have had to redesign their billing systems and imposed expensive IT changes on issuers and states, requiring creation of an operating billing system only for individual Exchanges and not for products sold in any other market. Commenters also agreed that the separate billing regulation would have required costly changes to other issuer operations such as invoice processing, collections, customer service support, and electronic data interchange (EDI) transactions with Exchanges. Commenters also agreed there would be added administrative costs of mailing separate bills in separate envelopes and collecting separate payments. Commenters also expressed concern that the highest costs from the separate billing regulation would have been concentrated in states that require abortion coverage. Some commenters noted that issuers have already incurred ongoing costs for printing and mailing,

additional staffing, and reprogramming billing systems and that the separate billing regulation already resulted in increased burden for issuers and consumers, widespread confusion by consumers and other stakeholders, and an increase in frustration and confusion around grace periods and terminations.

Supporting commenters also stated that the separate billing regulation would have been so burdensome on issuers and consumers that it would have impeded access to abortion coverage, which is a common and safe medical intervention, and a legally and constitutionally protected form of medical care in the United States. These commenters noted that some issuers would find the separate billing regulation so burdensome that they would either leave the Exchange or drop coverage for abortion care entirely. These commenters asserted that coverage for abortion care often means the difference between getting the health care that a consumer needs and being denied that care, and that individuals denied abortions are more likely to experience eclampsia, other serious medical complications, and death, remain in relationships where interpersonal violence is present, and suffer anxiety after being denied an abortion.

Commenters agreed that it would have had a disproportionate effect on consumer groups who already face barriers in navigating health insurance, particularly people of color, immigrants, individuals with LEP or low literacy and educational levels, and those living with visual disabilities and/or impairments. Commenters explained that restrictions to abortion coverage such as the separate billing regulation particularly harm BIPOC as well as LGBTQ+ individuals who disproportionately struggle with poverty and who are over-represented in the population of individuals receiving abortions. Commenters noted that 28 percent of individuals who receive abortions are Black and 25 percent are Latinx, while they represent only 13 percent and 18 percent of the U.S. population, respectively. These commenters also noted that the separate billing regulation would have exposed many of these individuals and families to untenable economic circumstances because, if issuers were to drop such abortion coverage, the costs would be transferred to consumers and such costs would likely disproportionately impact low-income women who already face barriers to accessing health care services. Commenters also asserted that termination of coverage due to confusion over payment of the second

¹²⁰ *California v. U.S. Dep't of Health & Hum. Servs.*, 473 F. Supp. 3d 992, 1003 (N.D. Cal. July

20, 2020) (citing *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016)).

bill would be especially problematic for consumers with critical medical needs such as cancer patients and survivors, as gaps in coverage may interrupt treatment schedules which could jeopardize outcomes in care.

Commenters also noted that repealing the separate billing regulation and interpreting section 1303 of the ACA in the least burdensome manner is consistent with both the Department's mission to "enhance the health and well-being of all Americans" and E.O. 14009, which directed HHS to review all existing regulations to determine whether they are inconsistent with the Administration's policy priority of "eliminating unnecessary difficulties to obtaining health insurance."

Commenters also expressed support that the proposal is consistent with E.O. 13985, which directed HHS to assess whether, and to what extent, its programs and policies "perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups."¹²¹

Commenters objecting to repeal of the separate billing regulation and codification of the pre-2019 policy asserted that justifying repeal of the policy based partially on a reassessment of burden ignores the issuers, states, Exchanges, and consumers for which separate billing regulation had no impact. For example, such commenters explained that the separate billing regulation had no effect on issuers, states, Exchanges, and consumers in states that prohibit insurance coverage of abortion services for which Federal funding is prohibited or on issuers that do not include such coverage in their plans for other reasons.

Objecting commenters broadly criticized HHS's cost estimates for the burden associated with the separate billing regulation, arguing that HHS failed to consider important factors, explore sufficient data, and make necessary estimates. These commenters asserted that HHS based its cost estimates on the projections from the 2019 Program Integrity Rule which commenters claim lack sufficient justification. For example, commenters asserted that HHS did not provide sufficient evidence that certain groups of people are more likely to be impacted by the separate billing regulation than others or that the burden will fall more heavily on marginalized communities. Such commenters added that, in any event, such arguments cannot justify violating the separate billing requirement that commenters argue is expressly required under section 1303.

Commenters also argued that HHS has not shown how repeal of the separate billing regulation and codification of the prior policy will add a financial benefit for either consumers or issuers that outweighs the harm caused to consumer transparency, conscience protections, and statutory compliance with section 1303. Such commenters asserted that the separate billing regulation would have rightly shifted the burden of complying with section 1303 away from individual consumers and onto issuers. Commenters also asserted that, without exploring further information, HHS cannot claim a full and complete savings of the estimated costs had the separate billing regulation been implemented.

Objecting commenters also alleged that, regardless of the extent of burden associated with the separate billing regulations on issuers, states, Exchanges, and consumers, any such burden is not unreasonable, but rather is necessary to ensure compliance with section 1303. Commenters objecting to repeal of the separate billing regulation also posited that HHS provided insufficient evidence to support the assertion that marginalized communities would be disproportionality burdened by the separate billing regulation had it been implemented.

Commenters also asserted that the cost estimates fail to address or take into account recent changes in the law made by the ARP. Commenters stated that millions of Americans are newly eligible for zero-dollar coverage under ARP but that, in states where all or most individual market plans cover abortion for which Federal funding is prohibited, consumers will not be able to purchase a zero-dollar premium plan because of section 1303's funding restrictions. Commenters therefore argued that individuals in such situations are already paying, in effect, a "separate bill" for that coverage and would not face additional burdens established by the separate billing regulation. Commenters raising this objection asked HHS to explain how the Department will enforce section 1303's funding restrictions for otherwise zero-premium Exchange plans and to provide a state-by-state analysis of the effects of the proposed rule.

Response: HHS agrees with commenters that the burden on stakeholders and consumers to comply with the separate billing regulation would have been overly burdensome if the policy had ultimately been implemented. HHS also agrees that the increased burden associated with issuers complying with the separate

billing regulation could have influenced whether a QHP issuer continues to offer coverage of abortion services for which Federal funding is prohibited in states that do not require it, an outcome which was also acknowledged in the 2019 Program Integrity Rule. HHS also agrees with commenters that, had the separate billing regulation been implemented, consumer confusion over receiving a separate bill for a relatively small amount of premium could have caused inadvertent loss of coverage and would have imposed significant burden on states and issuers to implement the new billing framework.

HHS generally disagrees with commenters contesting the estimated cost savings of repealing the separate billing regulation, particularly those claiming that the estimated cost savings are too high because they believe that the estimated burden in the 2019 Program Integrity rule was inflated. Some commenters noted that issuers have already incurred ongoing costs for printing and mailing, additional staffing, and reprogramming billing systems and that the separate billing regulation already resulted in increased burden for issuers and consumers, widespread confusion by consumers and other stakeholders, and an increase in frustration and confusion around grace periods and terminations. HHS acknowledges that some costs may have already been incurred by issuers and that the actual cost savings, especially for one-time IT related costs, may be lower than HHS estimates. Unfortunately, HHS does not have an estimate of costs already incurred by issuers and can only estimate savings going forward. HHS nonetheless continues to believe the timing of the courts' actions likely dissuaded issuers from assuming further costly administrative and operational burdens required to build the separate billing policy into their billing and IT systems. As the courts' nationwide invalidation of the policy prevented HHS from requiring initial implementation of the separate billing regulation, the potential consumer confusion over payment obligations, which could have inadvertently led to non-payment of enrollee premium and subsequent termination of consumer coverage, was also avoided. Furthermore, HHS continues to believe that requiring separate billing is unnecessary and overly burdensome to achieve compliance with section 1303 of the ACA. Section 1303 does not specify a method for compliance with the separate payment requirement, and HHS believes the new issuer compliance

¹²¹ 86 FR 7009 (Jan. 25, 2021).

options codified at § 156.280(e)(2)(ii) minimize stakeholder burden and protect against consumer confusion and potential loss of coverage.

HHS acknowledges that consumers who live in states where premiums for Exchange coverage cannot be fully paid for with APTC, such as states that require coverage of abortion services for which Federal funding is prohibited, will not have access to a silver plan with a zero-dollar premium, as further explained in the preamble to § 155.420(d)(16) of the proposed rule.¹²² However, HHS also notes that individual market QHP issuers covering abortion services for which Federal funds are prohibited offering coverage to consumers who qualify for zero-dollar premium plans are still required to comply with section 1303 of the ACA and all applicable requirements codified at § 156.280. HHS also notes that the ARP was enacted in 2021 and, therefore, the consumer cost and burden estimates in each respective rule regarding the separate billing regulation were based on the estimated number of all consumers enrolled in QHPs offering coverage for abortion and are reflective of the anticipated burden at that time.

HHS similarly disagrees with commenters questioning the validity of the cost estimates and cost-benefit analysis for repealing the separate billing regulation and codifying the prior acceptable methods for compliance with section 1303. In response to comments that objected to the omission of issuers that do not cover abortion services for which Federal funding is prohibited and states that ban such coverage, HHS notes that such an omission is appropriate as such issuers and states would not be impacted by the requirements or the high costs and burden from the separate billing regulation. The 2019 Program Integrity Rule included a detailed account of the anticipated financial and operational burdens from the separate billing regulation, estimates which were based upon plan and premium data, actuarial estimates, public comments from issuers and states directly regulated by the separate billing policy, and consumer enrollment figures. Those burdens are discussed in further detail in sections III., “Collection of Information Requirements,” and IV., “Regulatory Impact Analysis,” of that rule and explain from where such estimates are derived. Those burdens included one-time cost estimates for issuers and State Exchanges performing premium billing and payment processing for operational changes such as implementation of the

technical build to implement the necessary system changes to support separate billing and receipt of separate payments, which would require significant changes to current billing practice and pose increased challenges given the mid-plan year implementation timeline. The anticipated burden also included ongoing annual costs for sending a separate bill to impacted enrollees, associated record keeping, customer service, and compliance, as well as annual materials costs related to printing of and sending the separate bill. HHS also acknowledged that the separate billing regulation would impose burdens on State Exchange operations due to one-time technical changes such as updating online payment portals to accept separate payments and updating enrollment materials, as well as ongoing annual costs associated with increased customer service, outreach, and compliance.

The Program Integrity Rule also projected that FFEs would incur additional costs due to one-time technical changes and increased call volumes and additional customer services efforts. HHS also stated that QHP issuers were likely to consider these new costs when setting actuarially sound rates and that this would likely lead to higher premiums for enrollees. HHS also anticipated increased costs to consumers for the time required to read and understand the separate bills and to seek help from customer service if necessary, and additional time to read and send separate payments in subsequent months. In total, the projected burden to all issuers, states, State Exchanges performing premium billing and payment processing, the FFEs, and consumers totaled \$546.1 million in 2020, \$232.1 million in 2021, \$230.7 million in 2022, and \$229.3 million annually in 2023 and onwards.

As stated in the proposed rule, HHS has since reassessed these burdens and agree with commenters that the consumer confusion and new logistical obstacles from the separate billing regulation would disproportionately burden communities that already face barriers to accessing care, such as individuals with LEP, individuals with disabilities, rural residents, those with inconsistent or no access to the internet, those with low levels of health care system literacy, and individuals within other marginalized communities. The impact of these barriers to access for the aforementioned segments of consumers are routinely borne out in multiple studies and supported by readily

available data and evidence.¹²³ For example, the National Council on Disability concludes that, “[p]eople with disabilities experience more problems accessing health care than other groups, and these difficulties increase for those with the most significant disabilities and who are in the poorest health.”¹²⁴ Existing inequalities in access to health care resulting from those barriers would be exacerbated by the addition of further and unnecessary requirements that result in consumers receiving a second separate bill for a relatively miniscule amount with an arbitrary requirement to pay both bills in separate transactions. As many commenters noted, failure to pay the separate bill entirely due to consumer confusion could also lead to a complete loss of coverage, further exacerbating existing health disparities and jeopardizing health outcomes.¹²⁵ The 2019 Program Integrity Rule also acknowledged that the high burden associated with the separate billing regulation might result in issuers withdrawing coverage of abortion services for which Federal funds are prohibited altogether to avoid the associated burden, requiring some enrollees to pay for these services out-of-pocket. Based on a 2014 study, the average costs to patients for first-trimester abortion care was \$461, and anywhere from \$860 to \$1,874 for second-trimester abortion care.¹²⁶ Transferring these costs to enrollees could disproportionately impact low-income women for whom these out-of-pocket costs could represent a significant financial burden. In addition,

¹²³ See Rural Health, Centers for Disease Control and Prevention, available at <https://www.cdc.gov/chronicdisease/resources/publications/factsheets/rural-health.htm>; Accenture, The Hidden Cost of Healthcare System Complexity (2018), available at https://www.accenture.com/_acnmedia/pdf-104/accenture-health-hidden-cost-of-healthcare-system-complexity.pdf; The Current State of Health Care for People with Disabilities, The National Council on Disability, available at <https://www.ncd.gov/publications/2009/Sept302009#Overview>. See Victor G. Villagra et al., *Health Insurance Literacy: Disparities by Race, Ethnicity, and Language Preference*, American Journal of Managed Care (Mar. 2019), available at <https://www.ajmc.com/view/health-insurance-literacy-disparities-by-race-ethnicity-and-language-preference>.

¹²⁴ See The Current State of Health Care for People with Disabilities, The National Council on Disability, available at <https://www.ncd.gov/publications/2009/Sept302009#Overview>.

¹²⁵ See Health Coverage by Race and Ethnicity, 2010–2019, Kaiser Family Foundation, available at <https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/>.

¹²⁶ See Roberts, Sarah C. M., Heather Gould, Katrina Kimport, Tracy A. Weitz, and Diana Greene Foster, “Out-of-Pocket Costs and Insurance Coverage for Abortion in the United States,” *Women’s Health Issues*, vol. 24, no. 2 (2014): e211–e218.

low-income women may already face barriers to accessing quality health care due to their socioeconomic status, gender, sexual orientation, nationality, or race.¹²⁷ HHS believes proposing repeal of the separate billing regulation would remove these burdensome requirements and obstacles, promoting health equity.

Comment: Commenters supporting the proposal to repeal the separate billing regulation and codify the prior policy from the 2016 Payment Notice expressed support for reverting to an interpretation of section 1303 that is consistent with Congressional intent. Such commenters emphasized that, although Congress decided to treat abortion differently when passing section 1303, it did so specifically to ensure that private insurance plans could continue to decide whether or not to cover abortion in a state that did not ban such coverage. These commenters also noted that during the ACA debates and negotiations, Congress rejected amendments aimed at more stringent restrictions or prohibitions of abortion coverage. Commenters also supported repeal of the separate billing regulation, noting it would have interfered with flexibility provided to states under section 1303 of the ACA by interfering with states' requirements to offer or allow abortion coverage in their plans, which section 1303 expressly permits.

Commenters also noted that section 1303(b)(2)(E)(i) of the ACA designates state insurance commissioners as the entities responsible for monitoring, overseeing, and enforcing the provisions in section 1303 related to the segregation of funds for QHPs that cover abortion services for which Federal funding is prohibited.

Commenters supporting repeal of the separate billing regulation agreed that section 1303 does not expressly require a specific method for collecting the separate payment for abortion services for which Federal funding is prohibited. Commenters also highlighted that section 1303(b)(3)(B) of the ACA specifies that issuer notifications shall provide information only with respect to the total amount of the combined payments for abortion services for which Federal funding is prohibited and other services covered by the plan. Commenters therefore stated that requiring separate billing for these services directly contradicts section 1303(b)(3)(B) as it would have required issuers to separately notify the consumer on a monthly basis of the

portion of their premium attributable to coverage of abortion services for which Federal funds are prohibited.

Commenters also stated that codifying the pre-2019 options for compliance with the separate payment requirement comply with the section 1303(b)(2)(E) of the ACA, which states that health plans shall "comply with the segregation requirements in this subsection through the segregation of plan funds in accordance with applicable provisions of generally accepted accounting requirements, circulars on funds management of the Office of Management and Budget, and guidance on accounting of the Government Accountability Office." Specifically, commenters noted that generally accepted accounting requirements would permit one single bill outlining the separate charges for any covered abortion services for which Federal funding is prohibited. Commenters noted that requiring separate bills for each charge, as established in the 2019 Program Integrity Rule, goes too far, is against industry practice, and is not what section 1303 requires.

Commenters objecting to the proposal to repeal the separate billing regulation asserted that section 1303 is unambiguous in requiring a separate bill for coverage of abortion for which Federal funding is prohibited, and that any ambiguity is clarified by the legislative history of section 1303 of the ACA. Objecting commenters also stated that, prior to the separate billing regulation, HHS failed to enforce section 1303's separate payment requirements sufficiently, citing a 2014 Government Accountability Office (GAO) report that found issuer inconsistencies in compliance with section 1303 requirements¹²⁸ and a 2018 letter from Congress which cited the same GAO report.¹²⁹ Such commenters objected to repeal of the separate billing regulation, stating that requiring two separate bills would have addressed what commenters believed was insufficient enforcement of section 1303. Commenters argued that money that originates as a single payment and is later separated into separate allocation accounts is not separate within the meaning of section 1303 and that only with separation from intake to

expenditure can health care providers meaningfully ensure that abortion services are not being funded from the same pool of resources as other health care services. These commenters asserted that the separate billing regulations align best with the text of the ACA and the intent of Congress in including section 1303 by providing the most common-sense route to encourage consumers to make separate payments as required by statute and to maintain the segregation of funds from intake to expenditure. Commenters also stated that, according to Merriam-Webster Dictionary, the word "separate" means "to set or keep apart" and that this warrants an interpretation of section 1303 as requiring only separate bills. Objecting commenters also argued that section 1303(b)(2)(B)(i) of the ACA demonstrates that section 1303 requires separate billing by elaborating that in the case of a payroll deposit, a separate deposit is required. Commenters therefore assert that the fact that section 1303 expressly requires separate deposits for certain abortion coverage in the case of premiums paid through employee payroll deposits further supports the interpretation that issuers must collect all separate payments from individuals through separate transactions.

Response: HHS again emphasizes that multiple Federal district courts have already invalidated the separate billing regulation, preventing HHS from requiring its implementation.¹³⁰ HHS also continues to believe the changes to § 156.280(e)(2)(ii) offer issuers options for meaningful compliance with section 1303 and ensure appropriate segregation of funds required by statute, without imposing the operational and administrative burdens of the separate billing regulation and without causing additional consumer confusion and unintended losses of coverage, a position that is supported by the Federal district courts invalidating the separate billing regulation. HHS therefore disagrees with commenters' assertions that the other methods for complying with the separate payment requirement HHS is finalizing at § 156.280(e)(2)(ii) are in conflict with the requirements in section 1303.

Indeed, the preamble to the 2019 Program Integrity Rule acknowledged that receipt by a QHP issuer of a single premium payment for the entirety of the policy holder's coverage including

¹²⁸ U.S. Government Accountability Office, "Health Insurance Exchanges: Coverage of Nonexcepted Abortion Services by Qualified Health Plans," (Sept. 15, 2014), available at <http://www.gao.gov/products/GAO-14-742R>.

¹²⁹ Letter from Chris Smith, Member of Congress, to Alex Azar, Secretary, U.S. Department of Health and Human Services (Aug. 6, 2018), available at https://chrissmith.house.gov/uploadedfiles/2018-08-06_-_smith_letter_on_section_1303_-_abortion_funding_transparency.pdf.

¹³⁰ *Planned Parenthood of Maryland, Inc. v. Azar*, No. CV CCB-20-00361 (D. Md. July 10, 2020); *California v. U.S. Dep't of Health & Hum. Servs.*, 473 F. Supp. 3d 992 (N.D. Cal. July 20, 2020); *Washington v. Azar*, 461 F. Supp. 3d 1016 (E.D. Wash. 2020).

¹²⁷ See Disparities, Healthy People 2020, available at <https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities>.

abortion services for which Federal funds are prohibited did not preclude QHP issuer compliance with the section 1303 separate payment requirement. Although the separate billing regulation required QHP issuers to bill separately and make reasonable efforts to collect the payment separately, it also specified that QHP issuers would not be permitted to refuse a combined payment or terminate the policy on the basis of combined payment. The separate billing regulation is therefore ultimately nonessential to QHP issuer compliance with the separate payment requirement in section 1303 of the ACA, which does not expressly require that a separate bill be sent for coverage of abortions for which Federal funding is prohibited. Upon receiving a single premium payment inclusive of the portion of premium attributable to coverage of such services, the QHP issuer may treat that portion as a separate payment and disaggregate the amounts into the separate allocation accounts, consistent with § 156.280(e)(2)(iii). HHS believes this provides the requisite segregation of funds required by statute. HHS therefore believes that requiring QHP issuers to acquire the separate payment through sending separate bills and instructing consumers to pay in separate transactions is more restrictive than necessary, especially in light of the issuer and stakeholder burden and adverse consumer impacts the separate billing regulation could impose.

Although sending a separate bill to enrollees for these services is one way in which an issuer may satisfy the separate payment requirement as finalized at § 156.280(e)(2)(ii), it is not the only method contemplated by the plain reading of section 1303. HHS therefore agrees with commenters that it is unnecessary to restrict the acceptable methods for collecting these payments, especially in light of the substantial anticipated burden from the separate billing regulation, the risk of inadvertent coverage terminations that could result from consumer confusion due to receiving two monthly bills, the stakeholder reliance on the prior acceptable methods, and Federal district court concerns with barriers to appropriate and timely medical care as well as a lack of corresponding benefits.

The section 1303 provision that is colloquially referred to as the separate payment requirement is titled “Establishment of allocation accounts,” and is a subsection of a section titled “Prohibition on the use of Federal funds.”¹³¹ These sections detail issuer requirements for calculating the AV for

the portion of the premium attributable to coverage of abortion services for which Federal funds are prohibited, and require issuers to collect separate payments for this portion of the premium, segregate the funds, and deposit such funds into separate allocation accounts. Notably, these sections do not require that issuers satisfy these requirements by separately billing policy holders or instructing them to pay in separate transactions.

Lastly, HHS notes that not only is the 2014 U.S. GAO report that objecting commenters state is evidence of HHS non-enforcement of section 1303 of the ACA outdated, but also there is no evidence of ongoing issuer compliance issues with section 1303 of the ACA. In fact, the 2014 U.S. GAO report predates the 2016 Payment Notice, which is where HHS first clarified for issuers the acceptable methods for complying with the separate payment requirement which HHS is reinstating and codifying today. Further, the research to inform that report was conducted between February 2014 and September 2014, prior to the 2016 Payment Notice and during the first full year that the Exchanges began operating. As such, issuers were less likely to have fully implemented the compliance standards required under the ACA and were not yet aware of how HHS would further clarify and implement the separate payment requirement in the 2016 Payment Notice.

Section 1303 does not specify the method a QHP issuer must use to collect the separate payment.¹³² Consistent with the Federal district court decisions invalidating the separate billing regulation, HHS is therefore finalizing a revised policy at § 156.280(e)(2)(ii) that repeals the separate billing regulation and instead allows issuers to satisfy the separate payment requirement through methods consistent with section 1303 of the ACA. As finalized, § 156.280(e)(2)(ii) imposes no more burden on issuers, states, Exchanges, and consumers than is necessary, and removes unreasonable barriers to obtaining appropriate medical care.

IV. Provisions of the Proposed Rule for Section 1332 Waivers—Department of Health and Human Services and Department of the Treasury

A. 31 CFR Part 33 and 45 CFR Part 155—Section 1332 Waivers

Section 1332 of the ACA permits states to apply for a section 1332 waiver to pursue innovative strategies for providing their residents with access to

higher value, more affordable health coverage.

Under section 1332 of the ACA, the Secretary of HHS and the Secretary of the Treasury (collectively, the Secretaries) may exercise their discretion to approve a request for a section 1332 waiver only if the Secretaries determine that the proposal for the section 1332 waiver meets the following four requirements, referred to as the statutory guardrails: (1) The proposal will provide coverage that is at least as comprehensive as coverage defined in section 1302(b) of the ACA and offered through Exchanges established under title I of the ACA, as certified by the Office of the Actuary of CMS, based on sufficient data from the state and from comparable states about their experience with programs created by the ACA and the provisions of the ACA that would be waived; (2) the proposal will provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state's residents as would be provided under title I of the ACA; (3) the proposal will provide coverage to at least a comparable number of the state's residents as would be provided under title I of the ACA; and (4) the proposal will not increase the Federal deficit. The Secretaries retain their discretionary authority under section 1332 to deny waivers when appropriate given consideration of the application as a whole, even if an application meets the four statutory guardrails.

The Departments are also responsible under section 1332 for monitoring an approved section 1332 waiver's compliance with the statutory guardrails and for conducting evaluations to determine the impact of the section 1332 waiver. Specifically, section 1332 of the ACA requires that the Secretaries provide for and conduct periodic evaluations of approved section 1332 waivers.¹³³ The Secretaries must also provide for a process under which states with approved section 1332 waivers must submit periodic reports concerning the implementation of the state's waiver program.¹³⁴

In October 2018, the Departments issued the 2018 Guidance,¹³⁵ which provided additional guidance for states wishing to submit section 1332 waiver proposals regarding the Secretaries' application review procedures, pass-through funding determinations, certain analytical requirements, and operational

¹³¹ Section 1303(b)(2) and (b)(2)(B) of the ACA.

¹³² 84 FR 71674, 71683.

¹³³ See section 1332(a)(4)(B)(v) of the ACA.

¹³⁴ See section 1332(a)(4)(B)(iv) of the ACA.

¹³⁵ 83 FR 53575 (Oct. 24, 2018).

considerations.¹³⁶ The 2018 Guidance also included information regarding how the Departments will apply and interpret the section 1332 statutory guardrails when evaluating waiver applications. Furthermore, in part 1 of the 2022 Payment Notice final rule,¹³⁷ the Departments codified many of the major policies and interpretations outlined in the 2018 Guidance into the text of relevant section 1332 implementing regulations.

On January 28, 2021, President Biden issued E.O. 14009,¹³⁸ directing the Secretaries and the heads of all other executive departments and agencies with authorities and responsibilities related to Medicaid and the ACA to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether such agency actions are inconsistent with the policy set forth in section 1 of E.O. 14009. As part of this review, E.O. 14009 directed agencies to look at demonstrations and waivers, as well as demonstration and waiver policies that may reduce coverage under or otherwise undermine Medicaid or the ACA. As such, the Departments reviewed the 2012 Final Rule, the 2015 Guidance, the 2018 Guidance, and the policies implemented in part 1 of the 2022 Payment Notice final rule on section 1332 waivers to determine whether they are inconsistent with the policy intention of E.O. 14009 to protect and strengthen Medicaid and the ACA and to make high-quality health care accessible and affordable for every American.

In addition, on January 20, 2021, President Biden issued E.O. 13985,¹³⁹ directing that, as a policy matter, the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. As such, the Departments also reviewed the 2012 Final Rule, the 2015 Guidance, the 2018 Guidance, and the policies implemented in part 1 of the 2022 Payment Notice final rule on section 1332 waivers to assess whether, and to what extent, these policies may perpetuate systemic

barriers to opportunities and benefits for people of color and other underserved groups.

Upon review, the Departments determined that the 2012 Final Rule was generally consistent with the policy intentions of E.O. 14009 and E.O. 13985. However, the Departments determined that the 2018 Guidance and the policies implemented in part 1 of the 2022 Payment Notice final rule on section 1332 waivers were generally inconsistent with the policy intentions of E.O. 14009 and E.O. 13985. As explained in part 1 of the 2022 Payment Notice final rule and the proposed rule, the majority of commenters on both the 2018 Guidance and the 2022 Payment Notice Proposed Rule noted that both the 2018 Guidance and the incorporation of its guardrail interpretations into regulations could result in the Departments approving section 1332 waivers that would result in fewer residents in those states enrolling in comprehensive and affordable coverage, and that those interpretations do not represent the best fulfillment of Congressional intent behind the statutory guardrails. After further consideration of these comments as part of the Departments' reviews under E.O. 14009 and E.O. 13985, the Departments proposed to modify 31 CFR 33.108(f)(3)(iv)(A)–(C) and 45 CFR 155.1308(f)(3)(iv)(A)–(C) to generally remove the language incorporating the interpretation of the statutory guardrails first set forth in the 2018 Guidance from the text of the section 1332 regulations, including those that were finalized in part 1 of the 2022 Payment Notice final rule. In addition, the Departments proposed new interpretations and proposed amendments to regulations to provide supplementary information about the requirements that must be met for the approval of a section 1332 waiver, the Secretaries' application review procedures, certain analytical requirements, operational considerations, the calculation of pass-through funding, and amendments and extensions of approved waiver plans. The Departments discussed that the new proposed policies and interpretations, if adopted, would supersede those outlined in the 2018 Guidance and, where applicable, the preamble to part 1 of the 2022 Payment Notice final rule. The Departments also proposed amendments to the regulations that align with the revised interpretations of the guardrails.

In this final rule, the Departments are finalizing policies, interpretations, and regulatory amendments to provide clarity to states regarding the requirements and expectations of the

section 1332 waiver program for the approval, as well as for ongoing oversight, of approved waivers. The Departments received 262 comments on the section 1332 waiver proposals from a mix of stakeholders, including general advocacy organizations, disease advocacy organizations, states, issuers, providers, individuals, and other entities. The overwhelming majority of stakeholders supported the section 1332 waiver proposals and encouraged the Departments to finalize the policies as proposed. The Departments are generally finalizing the policies, interpretations, and regulatory amendments as proposed in order to encourage states to develop innovative waivers. Specifically, the Departments are finalizing modifications to 31 CFR 33.109(f)(3)(iv)(A)–(C) and 45 CFR 155.1308(f)(3)(iv)(A)–(C) to codify in regulation the manner in which the Departments will apply the comprehensiveness, affordability, and coverage guardrails. Relatedly, the Departments are adopting the proposed policy clarifications relating to the deficit neutrality guardrail. In addition, the Departments are adopting policy clarifications as outlined in the preamble to the proposed rule relating to coordinated waivers, application timing, requirements for the actuarial and economic analyses, implementation timeline and operational concerns, and public input on waiver proposals. The Departments are also finalizing modifications to 31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR 155.1320 to extend flexibilities in the public notice requirements and post-award public participation requirements for waivers under section 1332 beyond the COVID-19 PHE to allow similar flexibilities in the event of future emergent situations. The Departments also are finalizing the modifications to 31 CFR 33.120(a)(1) and (2) and 45 CFR 155.1320(a)(1) and (2) relating to waiver monitoring and compliance, to remove the reference, as codified under part 1 of the 2022 Payment Notice final rule, to interpretive guidance published by the Departments. Similarly, the Departments are finalizing the modifications to 31 CFR 33.128(a) and 45 CFR 155.1328(a) relating to periodic evaluation requirements, to remove the reference, as codified under part 1 of the 2022 Payment Notice final rule, to interpretive guidance published by the Departments. This rule also finalizes new regulation text at 31 CFR 33.122 and 45 CFR 155.1322 to codify in regulation details regarding the Departments' determination of pass-through funding for approved section

¹³⁶ The 2018 Guidance superseded guidance issued by the Departments in December 2015, which similarly provided information regarding the Secretaries' application review procedures, pass-through funding determinations, certain analytical requirements, operational considerations, and interpretations of the statutory guardrails. See 80 FR 78131, available at <https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf>.

¹³⁷ See 86 FR 6138.

¹³⁸ 86 FR 7793 (Feb. 2, 2021).

¹³⁹ 86 FR 7009 (Jan. 25, 2021).

1332 waivers. Through this rule, the Departments also finalize the addition of new regulation text at 31 CFR 33.130 and 45 CFR 155.1330 governing waiver amendment requests for approved section 1332 waivers and at 31 CFR 33.132 and 45 CFR 155.1332 governing waiver extension requests for approved section 1332 waivers.

As discussed in the proposed rule, the Departments are of the view that rescinding the 2018 Guidance, repealing the previous codification of its guardrail interpretations in part 1 of the 2022 Payment Notice final rule, and finalizing new policies and interpretations will align with the Administration's goals to strengthen the ACA and increase enrollment in comprehensive, affordable health coverage among the remaining underinsured and uninsured. These policies will further advance this Administration's goal of increasing access to coverage by empowering states to develop innovative health coverage options for their residents through section 1332 waivers that best fit the states' individual needs. The policies are also intended to provide more information and clarity regarding the interpretations, processes, and procedures the Departments would apply when reviewing new waiver applications and waiver amendment and extension requests, as well as making pass-through funding determinations for approved waivers. The Departments noted that all of the policies were designed to align with the Administration's commitment to protect and expand Americans' access to high-quality, comprehensive, and affordable health care coverage, and to ensure that systemic barriers to opportunities and benefits for people of color and other underserved groups are not perpetuated. In addition, the policies will further support the Administration's efforts to build on the ACA by meeting the health care needs created by the COVID-19 PHE, reducing individuals' health care costs, and making our health care system less complex to navigate. The Departments noted that, through section 1332 waivers, they aim to assist states with developing health insurance markets that expand coverage, lower costs, and make high-quality health care accessible for every American.¹⁴⁰ In light of E.O. 13985, the Departments also encourage states to develop waiver proposals that diminish barriers to

opportunities and benefits, such as health insurance coverage, for people of color and other underserved groups. For example, states may propose waiver programs that increase plan options for comprehensive coverage, reduce premiums, improve affordability, and address social determinants of health.

As under similar waiver authorities,¹⁴¹ the Departments note that the Secretaries reserve the right to further evaluate an approved waiver and suspend or terminate an approved waiver, in whole or in part, any time before the date of expiration, if the Secretaries determine that the state materially has failed to comply with the terms and conditions of the waiver, the section 1332 guardrails,¹⁴² or applicable laws and regulations, unless specifically waived.¹⁴³ In addition, states with approved waivers must come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.¹⁴⁴

1. Coordinated Waiver Process (31 CFR 33.102 and 45 CFR 155.1302)

Regulations at 31 CFR 33.102 and 45 CFR 155.1302 permit, but do not require, states to submit a single application for a section 1332 waiver and a waiver under one or more of the existing waiver processes applicable under titles XVIII, XIX, and XXI of the Social Security Act (the Act), or under any other Federal law relating to the provision of health care items or services, provided that the application is consistent with the procedures outlined in the 2012 Final Rule,¹⁴⁵ the procedures for demonstrations under section 1115 of the Act (section 1115 demonstrations), if applicable, and the procedures under any other applicable Federal law or regulations under which the state seeks a waiver.

Similar to the policies outlined in the 2018 Guidance, as well as in guidance previously published in December 2015 (2015 Guidance), the Departments' determination of whether a section 1332 waiver proposal satisfies the statutory guardrails set forth in section 1332 takes into consideration the projected impact of waivers of certain ACA provisions made pursuant to the section 1332

waiver. The Departments also consider related changes to the state's health care system that, under state law, are contingent only on the approval of the section 1332 waiver. For example, the Departments, in making their determination, would take into account the impact of a new, related state-run health benefits program that, under legislation enacted by the state, would be implemented only if the section 1332 waiver were approved.

The Departments did not propose any regulatory changes to 31 CFR 33.102 and 45 CFR 155.1302, but reiterated in the proposed rule the policy relating to the coordinated waiver process so states understand the process for submission and review of a coordinated waiver. As explained in the preamble to the proposed rule, the Departments are of the view that the policies outlined, which are in line with both the 2018 and 2015 Guidance, further advance E.O. 14009 because these policies aim to protect and strengthen Medicaid and the ACA and to make high-quality health care accessible and affordable for every American by specifying how a state may submit a coordinated waiver. Specifically, the Departments will not consider the potential impact of policy changes that are contingent on further state action, such as state legislation that is proposed but not yet enacted that would be in effect during the timeframe for the section 1332 waiver. For example, the Departments will not consider the potential impact of state legislation to expand Medicaid that is not yet enacted. The Departments also will not consider the impact of changes contingent on other Federal determinations, including approval of Federal waivers (such as waivers under section 1115 or titles XVIII, XIX, or XXI of the Act) pursuant to statutory provisions other than section 1332 of the ACA. Therefore, as proposed, the Departments will not take into account proposed changes to Medicaid or CHIP state plans, waivers, or demonstration projects that require separate Federal approval, such as changes in coverage or Federal Medicaid or CHIP spending that would result from a proposed section 1115 demonstration, regardless of whether the section 1115 demonstration proposal is submitted as part of a coordinated waiver application with a section 1332 waiver. Savings accrued under either proposed or current Medicaid or CHIP section 1115 demonstrations will not be factored into the assessment of whether a proposed section 1332 waiver meets the deficit neutrality requirement. The Departments' determination also will

¹⁴⁰ <https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/15/statement-by-president-joe-biden-on-the-2021-special-health-insurance-enrollment-period-through-healthcare.gov/>.

¹⁴¹ Section 1115 Waiver Demonstrations have similar authority.

¹⁴² See 31 CFR 33.120(d) and 45 CFR 155.1320(d) and STC 16 at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-NH-Approval-STCs.pdf>.

¹⁴³ See 31 CFR 33.120(a)(1) and 45 CFR 155.1320(a)(1).

¹⁴⁴ *Ibid.*

¹⁴⁵ See 77 FR 11700.

not take into account any proposed changes to the Medicaid or CHIP state plan that are subject to Federal approval.

As proposed, the Departments will take into account changes in Medicaid or CHIP coverage or in Federal spending on Medicaid or CHIP that would result directly from the proposed waiver of ACA provisions pursuant to section 1332, holding state Medicaid and CHIP policies constant. For example, if a state section 1332 waiver would result in more or less Medicaid spending, this impact will be considered in the Departments' assessment of the section 1332 waiver for the deficit neutrality guardrail.

Nothing in the proposed rule proposed to alter a state's authority to make changes to its Medicaid and CHIP policies consistent with applicable law. In addition, the proposed rule did not propose to alter the Secretary of HHS's authority or CMS's policy regarding review and approval of section 1115 demonstrations, and states should continue to work with the Center for Medicaid and CHIP Services (CMCS) on issues relating to section 1115 demonstrations or other Medicaid or CHIP authorities. A state may submit a coordinated waiver application as provided in 31 CFR 33.102 and 45 CFR 155.1302. The waiver applications included in a coordinated waiver application would each be reviewed by the applicable agency component independently according to the Federal laws and regulations that apply to each waiver application.

As the Departments receive and review waiver proposals, the Departments will continue to examine the types of changes, contingent on Federal approval, that will be considered in reviewing section 1332 waiver applications.

The following is a summary of the comments received and the Departments' responses related to the coordinated waiver process (31 CFR 33.102 and 45 CFR 155.1302).

Comment: The Departments received a few comments on coordinated waivers expressing general support of the policy clarifications regarding coordinated waivers. Some of the commenters also encouraged the Departments to consider additional flexibilities to further support coordinated waivers and reduce the burden on states. Commenters recommended allowing states to coordinate section 1115 demonstration projects and section 1332 waivers so that deficit neutrality is considered in light of both programs to result in greater savings. Commenters also recommended that the Departments

provide additional flexibility to states to demonstrate overall savings across both programs and for consumers/enrollees. The commenters contended that the proposal would otherwise have a negative impact on any new state-led innovation efforts through the section 1332 waiver process. Furthermore, another commenter encouraged the Departments to explore options for combined section 1115 demonstrations/ 1332 waivers to address affordability concerns for states, and to coordinate between Medicaid and Exchange programs to avoid gaps in coverage and ensure a seamless enrollment process.

Response: The Departments appreciate the comments and welcome the opportunity to work with states interested in pursuing coordinated waivers. States with specific proposals for coordinated waivers are encouraged to discuss proposals with the Departments early in the coordinated waiver development process. In regard to the commenter's suggestion that the Departments consider additional flexibilities concerning deficit neutrality (for the purposes of section 1332 waivers) and budget neutrality (for the purposes of section 1115 demonstrations) to further support coordinated waivers, the Departments note that there are differences between the section 1115 demonstration budget neutrality requirement and the section 1332 waiver deficit neutrality requirement. Section 1115 demonstrations are required to be budget neutral, meaning that Federal spending under the section 1115 demonstration cannot exceed the aggregate budget neutrality limit of what Federal spending would have been in absence of the section 1115 demonstration, and states are liable for additional demonstration spending over the budget neutrality limit. Section 1332 waivers are required by statute to not increase the Federal deficit. With regard to commenters' concerns that state innovation would be hindered without flexibility for states to demonstrate overall savings across Medicaid and Exchange programs, the Departments remind states that the Departments are committed to providing technical assistance to states and encourage innovative waiver proposals. Proposals may range from addressing affordability concerns, to closing gaps in coverage and ensuring a seamless enrollment process, and the particular approach taken will depend on each state's unique needs and circumstances.

As previously noted, the Departments did not propose any regulatory changes to 31 CFR 33.102 and 45 CFR 155.1302 in the proposed rule. After

consideration of the comments received, the Departments are adopting the proposed policies and interpretations related to the coordinated waiver process.

2. Section 1332 Application Procedures—Application Timing (31 CFR 33.108(b) and 45 CFR 155.1308(b))

Consistent with regulations at 31 CFR 33.108(b) and 45 CFR 155.1308(b), states are required to submit initial section 1332 waiver applications sufficiently in advance of the requested waiver effective date to allow for an appropriate implementation timeline. As explained in the proposed rule, the Departments did not propose any regulatory changes to 31 CFR 33.108(b) and 45 CFR 155.1308(b), but did propose through preamble policies related to the timing of initial section 1332 waiver application submissions that are consistent with policies outlined in the 2018 Guidance. As the Departments noted in the proposed rule, the proposed policies were intended to help states understand the requirements for submitting a section 1332 waiver application sufficiently in advance of the requested waiver effective date to allow for enough time for Federal review and to maintain smooth operations of the Exchange in the state. In addition, the proposed policies were intended to help states allow for enough time for implementation of their section 1332 waiver plan, and for affected stakeholders, including issuers of health insurance plans that may be affected by the waiver plan, to take necessary actions based on the approval of the waiver plan, particularly when the waiver impacts premium rates, if approved. As discussed in the proposed rule, some section 1332 waiver plans may require operational changes or accommodations to the Federal information technology platform or its operations, and the proposed policies would help ensure the state and the Departments are able to sufficiently plan in advance of the effective waiver date. The Departments proposed the following policies:

The Departments strongly encourage states interested in applying for section 1332 waivers, including coordinated waivers with section 1115 demonstrations, to engage with the Departments promptly for assistance in formulating an approach to a section 1332 waiver that meets the requirements of section 1332.

In order to help ensure timely decision-making regarding approval, the Departments advise that states should plan to submit their initial section 1332 waiver applications with enough time to

allow for public comment (as required by 31 CFR 33.112, 31 CFR 33.116(b), 45 CFR 155.1312, and 45 CFR 155.1316(b)), review by the Departments, and implementation of the section 1332 state plan as outlined in the waiver application. For example, for section 1332 waivers that impact the individual market, submission before or during the first quarter of the year prior to the year health plans affected by the section 1332 waiver would take effect would generally permit sufficient time for review and implementation of both the waiver application and affected plans, depending on the complexity of the proposal. The Departments note that they cannot guarantee approval of a section 1332 waiver submission or a state's request for expedited review and will continue to review applications consistent with the timeline requirements outlined in the regulations and statute.¹⁴⁶ The Departments encourage states to work with the Departments on formulating timeframes that take into account the states' legislative sessions and timing of health plan rate filings if the section 1332 waiver is projected to have any impact on premiums. If a state's section 1332 waiver application includes potential operational changes or accommodations to the Federal information technology platform or its operations, the Departments note that additional time for review and implementation of the waiver application may be needed. The Departments also encourage states to engage with the Departments early in the process to determine whether Federal infrastructure can accommodate technical changes that support their requested flexibilities, as discussed elsewhere in this preamble.

The following is a summary of the comments received regarding the Departments' proposed policies and the Departments' responses.

Comment: The Departments received one comment, which was in support of the proposal. The commenter applauded the Departments for encouraging states to engage with the Departments early in the waiver process and consider the implementation timeline as part of the waiver development and application process.

Response: The Departments appreciate the commenter's support. After consideration of the comments received, the Departments are adopting the proposed policies relating to section 1332 application procedures and timing.

3. Section 1332 Application Procedures—Statutory Guardrails (31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv))

The Departments proposed to modify 31 CFR 33.108(f)(3)(iv)(A)–(C) and 45 CFR 155.1308(f)(3)(iv)(A)–(C) to set forth revised interpretations of the comprehensiveness, affordability, and coverage guardrails. In addition, the Departments proposed to adopt new policies and interpretations with regard to the statutory guardrails that, if finalized, would supersede and rescind those outlined in the 2018 Guidance. The proposed guardrail interpretations were largely in line with those in the 2015 Guidance. The Departments also proposed to modify 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) to remove the reference, as codified under part 1 of the 2022 Payment Notice final rule, to interpretive guidance published by the Departments.

As discussed in the proposed rule, the 2018 Guidance aimed to allow states to pursue section 1332 waivers with the goals of increasing consumer choice and promoting private market competition. In particular, in the 2018 Guidance, the Secretaries explained that their interpretations of the statutory guardrails were meant to remove restrictions that could limit consumer choice by allowing states to provide access to health insurance coverage at different price points and benefits levels, including less comprehensive plans that states considered to be better suited to consumer needs. Specifically, the 2018 Guidance interpreted the comprehensiveness and affordability guardrails to be satisfied if comprehensive and affordable coverage were *available* to consumers, without regard to who would actually enroll in such coverage. In addition, the 2018 Guidance instructed that these two guardrails must be evaluated together. The 2018 Guidance explained that it is not enough to make available some coverage that is comprehensive but not affordable, while making available other coverage that is affordable but not comprehensive. Thus, the Departments stated that a state plan would comply with the comprehensiveness and affordability guardrails, consistent with the statute, if it makes coverage that is both comprehensive and affordable *available* to a comparable number of otherwise qualified residents as would have had such coverage available absent the waiver.

In the 2018 Guidance, the Departments also stated that section 1332(b)(1)(C) of the ACA requires that a

state's plan under a section 1332 waiver will provide coverage "to at least a comparable number of its residents" as would occur without the waiver.¹⁴⁷ The 2018 Guidance further noted that the text of the coverage guardrail provision of the statute is silent as to the type of coverage that is required. Accordingly, in the 2018 Guidance, the Departments explained they would consider section 1332 waivers to satisfy the coverage guardrail requirement if at least as many state residents were projected to be enrolled in comprehensive and less comprehensive health plans combined under the waiver as would be enrolled without the waiver. Under that interpretation, the Departments could approve a state's section 1332 waiver designed to promote residents' enrollment in less comprehensive or less affordable coverage to promote choice. As long as a comparable number of residents were projected to be covered as would have been covered absent the waiver, the coverage guardrail would be met.¹⁴⁸

In part 1 of the 2022 Payment Notice final rule, the Departments codified the 2018 Guidance interpretation of the guardrails into the text of the section 1332 implementing regulations. Specifically, the Departments added regulatory language in 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A), explaining that the Departments would consider the comprehensive coverage guardrail to be met by a state section 1332 waiver plan if the plan would provide consumers access to coverage options that are at least as comprehensive as the coverage options provided without the waiver, to at least a comparable number of people as would have had access to such coverage absent the waiver. The final rule also added language to 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B) providing that the Departments would consider the affordability requirement to be met by a state section 1332 waiver plan that would provide consumers access to coverage options that are at least as affordable as the coverage options provided without the waiver, to at least a comparable number of people as would have had access to such coverage absent the waiver. These modifications

¹⁴⁷ 83 FR at 53577.

¹⁴⁸ The Departments note that the policies and interpretations in the 2018 Guidance were in line with the Administration's priorities at the time. In particular, the 2018 Guidance noted that the Secretaries would consider favorably section 1332 waiver applications that advanced specific principles and noted that the Secretaries aimed to provide states maximum flexibility. See 83 FR at 53576.

¹⁴⁶ 31 CFR 33.108 and 45 CFR 155.1308; Section 1332(d)(1) of the ACA.

also provided, consistent with the 2018 Guidance and the Administration's priorities at the time, that the Departments would consider the comprehensiveness and affordability guardrails met if a section 1332 waiver plan provides *access* to coverage that is as comprehensive and affordable as coverage forecasted to have been available in the absence of the waiver, and is projected to be available to a comparable number of people under the waiver, as opposed to the actual number of people enrolled in comprehensive and affordable coverage as under the 2015 Guidance. The final rule also added regulatory language to 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) providing that, for purposes of the coverage guardrail, "coverage" refers to minimum essential coverage as defined in 26 U.S.C. 5000A(f) and 26 CFR 1.5000A-2, and health insurance coverage as defined in 45 CFR 144.103.

As noted in the proposed rule, a majority of commenters on both the 2018 Guidance and the 2022 Payment Notice proposed rule were concerned that the 2018 Guidance and its proposed codification would undermine the congressional intent underlying the section 1332 guardrails and effectively codify policy they believe is based on a misapplication of the statutory guardrails. The commenters were concerned that the interpretation of the availability of comprehensive and affordable coverage in the 2018 Guidance would result in fewer residents enrolled in comprehensive and affordable coverage. Other commenters asserted that the interpretation of the availability of comprehensive and affordable coverage for the coverage guardrail allows for a disjointed application of the guardrails whereby a state can meet the coverage guardrail, while its waiver plan reduces the overall comprehensiveness and affordability of coverage in a state. A few commenters recommended rescinding and abandoning the 2018 Guidance completely in favor of returning to the prior interpretation of the guardrails in the 2015 Guidance. In addition, some commenters also expressed concern that alternative coverage options, which would qualify for the purposes of meeting the coverage guardrail under the 2018 Guidance, are not subject to the same limitations as comprehensive coverage in terms of consumer protections. For instance, alternative plan options generally lack financial limitations like out-of-pocket maximums and annual/lifetime limits, and, if consumers covered by alternative

plan options experience unexpected, potentially-catastrophic health events, they are likely to pay substantially more out-of-pocket to cover incurred costs. Further, commenters also raised concerns that alternative plans can terminate or deny coverage based on health status, which would tend to affect high-risk individuals. Coupled with the diminished affordability of comprehensive coverage, this possibility puts high-risk individuals at great risk of going without effective coverage.

In the proposed rule, the Departments proposed changes to 31 CFR 33.108 and 45 CFR 155.1308 to incorporate revised interpretations of the statutory guardrails. The decision to rescind those interpretations was based on further consideration of commenters' concerns that the proposals are a better interpretation of section 1332(b)(1)(A)–(C), and the Departments' reviews under E.O. 14009, which was intended to strengthen the ACA and expand access to high-quality health care, and E.O. 13985, which was intended to pursue a comprehensive approach to advancing equity for all. The Departments concluded that the interpretations of section 1332's comprehensiveness, affordability, and coverage guardrails codified in part 1 of the 2022 Payment Notice final rule could permit section 1332 waivers that do not result in a comparable number of residents overall being enrolled in coverage that is at least as affordable and as comprehensive as they would have enrolled in without the waiver. As discussed in more detail later in this preamble, the Departments' changes are intended to align with the President's instruction in E.O. 14009 to adopt policies to strengthen the implementation of the ACA and remove any barriers that those policies may create for expanding coverage, lowering costs, and making high-quality health care accessible for every American.

The Departments determined that the guardrail interpretations codified in part 1 of the 2022 Payment Notice final rule were inconsistent with the Departments' goal of ensuring that the guardrails should be focused on the types of coverage residents actually purchase such that individuals *are enrolled* in affordable, comprehensive coverage and not just that there is generalized *access* to such coverage. The Departments note that plans that could be offered to individuals under section 1332 waivers applying the interpretations codified in the part 1 of the 2022 Payment Notice final rule could allow state section 1332 waivers that would result in more individuals enrolling in medically

underwritten plans¹⁴⁹ that offer only limited benefits, charge higher out-of-pocket costs, or both, which is inconsistent with the goal of the E.O. 14009 to reduce barriers for expanding comprehensive affordable coverage. Allowing more individuals to be in medically underwritten plans could also have a disparate impact on vulnerable populations, especially people of color and those who are in poverty, those who are underserved, and those with pre-existing conditions, which is inconsistent with the goal of E.O. 13985.

Additionally, the Departments are of the view that the section 1332 waiver proposals that could be available under the guardrail interpretations in the 2018 Guidance and codified in part 1 of the 2022 Payment Notice final rule may also conflict with E.O. 14009. For example, the *Section 1332 State Relief and Empowerment Waiver Concepts Discussion Paper* (November 2018 Discussion Paper)¹⁵⁰ included waiver concepts that were intended to foster discussion with states by illustrating how states might take advantage of new flexibilities provided in the 2018 Guidance. The Departments also are of the view that some of these waiver concepts, which rely upon the 2018 Guidance interpretation of the guardrails, are not in line with E.O. 14009 goals to protect and strengthen Medicaid and the ACA and to make high-quality health care accessible and affordable for every American. For example, the *Adjusted Plan Options* section 1332 waiver concept included in the 2018 Discussion Paper would permit states to have the flexibility to provide state financial assistance for non-QHPs.

¹⁴⁹ Health insurance issuers medically underwrite policies to try to ascertain prospective enrollees' health statuses when they are applying for health insurance coverage in order to determine whether to offer these individuals coverage, or at what price, and with what exclusions or limits, to offer coverage. (<https://www.healthcare.gov/glossary/medical-underwriting/>). Since 2014, however, medical underwriting is no longer permitted in the individual or small group markets with respect to non-grandfathered health insurance coverage, due to ACA rules. Instead, all such individual and small group plans are guaranteed issue. Guaranteed issue is a requirement that health insurance issuers must permit any individual to enroll regardless of health status, age, gender, or other factors that might predict the use of health services, subject to certain specified exceptions. Guaranteed issue does not limit how much individuals can be charged if they enroll in coverage. <https://www.healthcare.gov/glossary/guaranteed-issue/>. However, the ACA's community rating protections prevent health insurance issuers from varying premiums within a geographic area based on gender, health status or other factors not specified in the statute with respect to non-grandfathered individual and small group plans. <https://www.healthcare.gov/glossary/community-rating/>.

¹⁵⁰ <https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/Waiver-Concepts-Guidance.PDF>.

A section 1332 waiver proposal that includes this concept could potentially increase coverage in non-QHPs and potentially decrease enrollment in comprehensive coverage plans by allowing consumers to use a state subsidy towards catastrophic plans, individual market plans that are not QHPs, or plans that do not fully meet ACA requirements. This waiver concept is inconsistent with E.O. 14009, as it would likely result in consumers enrolling in non-QHPs and plans that do not fully meet ACA requirements, thereby increasing barriers for expanding comprehensive affordable coverage and potentially decreasing enrollment in comprehensive coverage. Further, commenters to the 2018 Guidance expressed generalized concern that the 2018 Guidance permitted alternative coverage options that can be underwritten and do not meet EHB standards. In addition, commenters were concerned that measures taken to facilitate coverage in alternative plan options (for example, allowing the use of subsidies for such coverage) would result in fewer comprehensive plans on the market, and that those comprehensive plans would become less affordable. In light of E.O.s 13985 and 14009 and concerns raised by commenters, the Departments proposed new policies that would allow states flexibility to develop waiver plans to meet their needs and expand coverage, lower costs, and increase access to high-quality health care with comprehensive benefits.

Given current policy goals, as well as the Departments' further consideration of comments received on the 2022 Payment Notice, the Departments proposed to revise policies for how the Departments would evaluate whether a state's section 1332 waiver plan satisfies each of the guardrails, as outlined in more detail later in this section. Overall, the Departments proposed that the "coverage" to be provided and evaluated in each guardrail should be interpreted the same way in each subparagraph of section 1332(b)(1)(A)–(C) of the ACA for consistency. Thus, the Departments proposed in 31 CFR 33.108(f)(3)(iv)(A) through (C) and 45 CFR 155.1308(f)(3)(iv)(A) through (C) that, to be approved, a waiver must be projected to provide coverage that is as comprehensive and affordable as would have been provided absent the waiver and to the same number of residents.

Similarly, given the current COVID–19 PHE, this Administration is focused on the response to the PHE and on helping increase enrollment in comprehensive, affordable health insurance coverage. The ARP made

numerous changes to the ACA to expand access to comprehensive health insurance coverage and lower costs. Specifically, the ARP temporarily expanded eligibility for and increased the value of APTC/PTC, enabling previously ineligible consumers to qualify for help paying for Exchange coverage and increasing assistance to eligible individuals already enrolled in Exchange plans. As discussed in the proposed rule, these changes have already increased enrollment through the Exchanges,¹⁵¹ and the Departments are of the view that this law will continue to increase enrollment through the Exchanges as the ARP's enhanced subsidies lower the costs of coverage for millions of Americans and change the incentives to seek and maintain comprehensive health insurance coverage. In addition, increased affordability and expansion of access to comprehensive health insurance coverage will better support enrollment of historically uninsured communities—especially those who have faced significant health disparities—in such coverage, thereby improving access to health care during and beyond the COVID–19 PHE. This Administration has also sought to strengthen the ACA and increase enrollment by directing the establishment of a special enrollment period, which was open from February 15, 2021 through August 15, 2021, for Exchanges using the *HealthCare.gov* platform (COVID–19 special enrollment period). Over 1.5 million Americans had already signed up for coverage on *HealthCare.gov* during the COVID–19 special enrollment period at the time of the proposed rule and that number has increased to 2.5 million.¹⁵² To promote the special enrollment period, CMS spent approximately \$100 million on outreach and education, including broadcast, radio, and digital advertising to reach the uninsured, and also launched parallel outreach efforts through stakeholders and partners to increase education and awareness across communities on the COVID–19 special enrollment period.¹⁵³ Earlier

¹⁵¹ 2021 Marketplace Special Enrollment Period Report, June 14, 2021 <https://www.cms.gov/newsroom/fact-sheets/2021-marketplace-special-enrollment-period-report-2>.

¹⁵² See <https://www.cms.gov/newsroom/fact-sheets/2021-marketplace-special-enrollment-period-report-3> and <https://www.cms.gov/newsroom/fact-sheets/2021-marketplace-special-enrollment-period-report-4>.

¹⁵³ On January 28, 2021, CMS announced \$50 million for outreach and marketing for the COVID–19 special enrollment period: <https://www.cms.gov/newsroom/fact-sheets/2021-special-enrollment-period-response-covid-19-emergency>. On April 1, 2021 HHS announced an additional \$50 million to further bolster the COVID–19 special enrollment period campaign and promote the lower premiums

this year, CMS made approximately \$2.3 million in additional funding available to current Navigator grantees in FFEs to support the outreach, education, and enrollment efforts around the COVID–19 special enrollment period.¹⁵⁴ Additionally, on August 27, 2021, CMS awarded \$80 million in grant funding to 60 Navigator grantees in 30 states with an FFE for the 2022 plan year.¹⁵⁵ This represents an eight-fold increase in funding from the previous year. Taken together, these policies, including the increased subsidies available under the ARP, the COVID–19 special enrollment period, and the increased Federal investment in the FFE Navigator program, have already led to, and are expected to continue to lead to, increased enrollment through the Exchanges.

As noted in the proposed rule, the Departments are of the view that rescinding the 2018 Guidance, repealing the previous codification of its guardrail interpretations in part 1 of the 2022 Payment Notice final rule, and proposing new policies and restoring prior interpretations aligns with the Administration's goals to strengthen the ACA and increase enrollment in comprehensive, affordable health coverage among the remaining underinsured and uninsured. The Departments also noted that they are of the view that during a pandemic, as Americans continue to battle COVID–19 and millions of Americans are facing uncertainty and experiencing new health problems, it is even more critical that Americans have meaningful access to high-quality, comprehensive and affordable health coverage options.

The Departments also proposed to modify 31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv) to remove the reference, as codified under part 1 of the 2022 Payment Notice final rule, to interpretive guidance published by the Departments. The Departments noted that they are of the view that the proposal aligns with the Departments' efforts to provide supplementary information about the requirements that must be met for the approval of a

under the ARP: <https://www.cms.gov/newsroom/press-releases/hhs-secretary-becerra-announces-reduced-costs-and-expanded-access-available-marketplace-health>.

¹⁵⁴ <https://www.cms.gov/newsroom/press-releases/cms-announces-additional-navigator-funding-support-marketplace-special-enrollment-period>.

¹⁵⁵ <https://www.cms.gov/newsroom/press-releases/cms-announces-80-million-funding-opportunity-available-navigators-states-federally-facilitated-0>.

<https://www.cms.gov/newsroom/press-releases/biden-harris-administration-quadruples-number-health-care-navigators-ahead-healthcaregov-open>.

section 1332 waiver and the Secretaries' application review procedures. Because the Departments are of the view that the 2018 Guidance and its incorporation into regulations could result in the Departments approving section 1332 waivers that would result in fewer residents in those states enrolling in comprehensive and affordable coverage, that those interpretations do not represent the best fulfillment of congressional intent behind the statutory guardrails, that they are inconsistent with the policy intentions of E.O. 14009 and E.O. 13985, and that it is appropriate to address concerns raised by commenters on the 2018 Guidance, the Departments proposed to remove references to the 2018 Guidance.

As proposed, the Departments would rely upon the statute and regulations, as well as the Departments' interpretive policy statements as outlined in the applicable notice and comment rulemaking, in reviewing section 1332 waiver applications.

The Departments sought comment on the proposals. The Departments also solicited comment on whether there are policies that meet the statutory guardrails of section 1332 waivers that the Departments could consider that would encourage states to find innovative ways to use section 1332 waivers to focus on equity and expand access to comprehensive coverage for their residents. In addition, the Departments considered whether any affected parties could be impacted by the proposed changes in policy interpretations outlined in this rule. This rule does not alter any of the requirements related to state innovation waiver applications, compliance and monitoring, or evaluation in a way that would create any additional costs or burdens for states submitting proposed waiver applications or those states with approved waiver plans that has not already been captured in prior burden estimates. As such, the Departments are of the view that both states with approved section 1332 waivers and states that are considering section 1332 waivers would continue to comply with the requirements noted earlier without creating any additional costs or burdens that have not already been accounted for in prior impact estimates of benefits and costs.

The following is a summary of the general comments received and the Departments' responses related to the section 1332 application procedures—statutory guardrails (31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv)).

Comment: The overwhelming majority of commenters were supportive

of the proposed changes to the policies and interpretations related to the statutory guardrails. Commenters encouraged the Departments to finalize the statutory guardrail proposals in order to establish strong protections for consumers so that states are not able to use section 1332 waivers to take away coverage or force people into high-cost health plans. Furthermore, commenters supported the policies and interpretations relating to the Departments' commitment to ensuring that waivers must not adversely affect vulnerable and underserved populations. A few commenters noted that the change in policies and interpretations would not affect approved waivers and supported the Departments finalizing the statutory guardrail policies and interpretations as proposed.

Response: The Departments appreciate commenters' support and agree that it is important to adopt policies that strengthen the ACA and increase enrollment in comprehensive, affordable health coverage. After consideration of the comments received, the Departments are finalizing as proposed regulation text at 31 CFR 33.108(f)(3)(iv)(A)–(C) and 45 CFR 155.1308(f)(3)(iv)(A)–(C), as well as adopting the new underlying statutory guardrail policies and interpretations described in this preamble.

Comment: A few commenters were concerned that the proposed changes to the policies and interpretations related to the statutory guardrails would be overly restrictive. These commenters were concerned that these proposed changes would limit state innovation and would be too restrictive for states to meet. Instead, these commenters expressed support for the 2018 Guidance guardrail interpretations, in particular the *access* standard. One commenter recommended that the 2018 Guidance guardrail interpretation for the *access* standard be expanded to the coverage guardrail as well.

Some of these commenters also took the position that the proposed changes to the policies and interpretations related to the statutory guardrails would undermine Congress' intent to give states a meaningful level of flexibility to develop and implement new health programs. They contended that the proposals only allow a waiver from the requirements of the ACA if the waiver meets the requirements of the ACA, thereby significantly diminishing state flexibility. Additionally, one commenter expressed concern that, by limiting consumer choice, the proposal would have a detrimental impact on vulnerable populations and "ignores how waiver

flexibility may allow states to better tailor plans for people with greater health needs." ¹⁵⁶

Response: The Departments appreciate these comments, but disagree that the proposed guardrail policies and interpretations are overly restrictive and will limit state flexibility to provide access to comprehensive, affordable coverage. These policies and interpretations only limit states' flexibility to adopt section 1332 waiver plans that promote coverage that is not comprehensive (such as medically underwritten plans) at the expense of comprehensive coverage options. The Departments are of the view that the policies and interpretations finalized in this rule will allow states to develop proposals to promote comprehensive affordable coverage and restrict waiver proposals that would result in enrollment in less comprehensive coverage that may leave consumers exposed to high out-of-pocket costs. The Departments are committed to working with states to develop innovative waiver plans to address health care needs in a particular state. As discussed in the preambles to the proposed rule and this final rule, the Departments have determined that the guardrail interpretations codified in part 1 of the 2022 Payment Notice final rule are inconsistent with the Departments' goal of ensuring individuals are enrolled in affordable, comprehensive coverage and not just that there is generalized access to such coverage. The decision to rescind these interpretations is based on the Departments' goal to ensure enrollment in comprehensive coverage and further consideration of previous comments and whether the replacement proposals are a better interpretation of section 1332(b)(1)(A)–(C), as well as the Departments' reviews under E.O. 14009, which is intended to strengthen the ACA and expand high-quality health care, and E.O. 13985, which is intended to pursue a comprehensive approach to advancing equity for all. The Departments' proposed statutory guardrail policies and interpretations, which are being finalized as proposed, are intended to align with the President's instruction in E.O. 14009 to adopt policies to strengthen the implementation of the ACA and remove any barriers that those policies may create for expanding coverage, lowering costs, and making high-quality health care accessible for every American. Furthermore, in line with E.O. 14009, this Administration is focused on ensuring high-quality health care is

¹⁵⁶ Center of the American Experiment comment letter on proposed rule.

accessible and affordable for every American. Therefore, as explained in the preambles to the proposed rule and this final rule, the Departments are of the view that the comprehensiveness and affordability guardrails should focus on the types of coverage residents actually purchase, rather than the types of coverage to which residents have access.

The Departments are also of the view that the policies and interpretations adopted in this preamble do not limit consumer choice and instead further the goal of ensuring individuals are enrolled in affordable, comprehensive coverage and not just that there is generalized access to such coverage. As discussed in the preambles to the proposed rule and this final rule, the plans that could be offered to individuals under section 1332 waivers when applying the interpretations codified in the part 1 of the 2022 Payment Notice final rule could allow state section 1332 waivers that would result in more individuals enrolling in medically underwritten plans that offer only limited benefits, charge higher out-of-pocket costs, or both, which is inconsistent with the goal of the E.O. 14009 to reduce barriers for expanding comprehensive affordable coverage. Allowing more individuals to enroll in medically underwritten plans could also have a disparate impact on vulnerable populations, especially people of color and those who are in poverty, those who are underserved, and those with pre-existing conditions, which is inconsistent with the goal of E.O. 13985. Further, waivers that result in more individuals enrolling in medically underwritten plans could also be detrimental to those who have chronic conditions or greater health needs. The policies and interpretations adopted in this preamble and regulations finalized in this rule will help decrease barriers for expanding comprehensive affordable coverage and potentially increase access to and enrollment in high-quality health care with comprehensive benefits. However, at the same time, the Departments note that the changes in policies and interpretations adopted in this preamble do not limit or otherwise establish new requirements or restrictions on other currently available coverage options. Therefore, the Departments generally disagree with commenters' assertions that the new statutory guardrail policies and interpretations will limit consumer choice, as consumers will continue to have access to the same coverage options, both on and off Exchange, as they do today.

After consideration of the comments received, the Departments are adopting

the new policies and interpretations described in this preamble with regard to the statutory guardrails and are finalizing the regulatory changes relating to the statutory guardrails (31 CFR 33.108(f)(3)(iv) and 45 CFR 155.1308(f)(3)(iv)) as proposed. Each of the statutory guardrails is addressed further later in this section of this preamble, along with summaries of and responses to comments on each of the individual guardrails.

a. Comprehensive Coverage (31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A))

The Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A) to set forth a revised interpretation of the comprehensiveness guardrail. In addition, the Departments proposed, through preamble, policies and interpretations relating to the requirements for the comprehensive coverage guardrail that are similar to the policies and interpretations outlined in the 2015 Guidance. Specifically, the Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A) such that to satisfy the comprehensive coverage requirement, the Departments, as applicable, must determine that the section 1332 waiver will provide coverage that is at least as comprehensive overall for residents of the state as coverage absent the waiver.

The Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A) for the comprehensiveness guardrail as follows:

To meet the comprehensiveness guardrail, health care coverage under a section 1332 waiver is required to be forecast to be at least as comprehensive overall for residents of the state as coverage absent the waiver.

As proposed, the Departments' policies and interpretations related to the comprehensiveness guardrail are as follows: Comprehensiveness refers to the scope of benefits provided by the coverage and would be measured by the extent to which coverage meets the requirements for EHBs as defined in section 1302(b) of the ACA and offered through Exchanges established by Title I of the ACA, or, as appropriate, Medicaid or CHIP standards. The impact on all state residents would be considered, regardless of the type of coverage they would have had absent the section 1332 waiver.

Comprehensiveness will be evaluated by comparing coverage under the section 1332 waiver to the state's EHB-

benchmark plan applicable for the plan year pursuant to 45 CFR 156.111, as well as to, in certain cases, the coverage provided under the state's Medicaid or CHIP programs.¹⁵⁷ A section 1332 waiver will not satisfy the comprehensiveness requirement if the waiver decreases: (1) The number of residents with coverage that is at least as comprehensive as the EHB-benchmark plan in all ten EHB categories; (2) for any of the ten EHB categories, the number of residents with coverage that is at least as comprehensive as the benchmark in that category; or (3) the number of residents whose coverage includes the full set of services that would be covered under the state's Medicaid or CHIP programs, holding the state's Medicaid and CHIP policies constant. That is, the section 1332 waiver cannot decrease the number of individuals with coverage that satisfies EHB requirements, the number of individuals with coverage of any particular category of EHB, or the number of individuals with coverage that includes the services covered under the state's Medicaid or CHIP programs.

Assessment of whether a section 1332 waiver proposal meets the comprehensiveness requirement will also take into account the effects across different groups of state residents, and, in particular, effects on vulnerable and underserved residents, including low-income individuals, older adults, those with serious health issues or who have a greater risk of developing serious health issues, and people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.¹⁵⁸ A section 1332 waiver will be highly unlikely to be approved by the Secretaries under the

¹⁵⁷ In the 2019 Payment Notice, HHS provided states with substantially more options in the selection of an EHB-benchmark plan. Instead of being limited to 10 options, states are now able to choose from the 50 EHB-benchmark plans used for the 2017 plan year in other states or select specific EHB categories, such as drug coverage or hospitalization, from among the categories in the EHB-benchmark plan used for the 2017 plan year in other states. Additionally, states are able to build their own set of benefits that could potentially become their EHB-benchmark plan, subject to certain scope of benefits requirements.

¹⁵⁸ These groups include individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

interpretation outlined in the preambles to the proposed rule and this final rule if the waiver would reduce the comprehensiveness of coverage provided to these types of vulnerable or underserved groups, even if the waiver maintained comprehensiveness in the aggregate. This condition generally must be forecast to be met in each year that the section 1332 waiver would be in effect.

Consistent with 31 CFR 33.108(f) and 45 CFR 155.1308(f), the section 1332 waiver application must include analysis and supporting data that establishes that the section 1332 waiver satisfies this requirement. This includes an explanation of how the benefits offered under the section 1332 waiver differ from the benefits provided absent the waiver (if the benefits differ at all) and how the state determined the benefits to be as “comprehensive.”

As discussed previously in the preamble to the proposed rule, the policies and interpretations of the comprehensiveness guardrail outlined in the 2018 Guidance and codified in part 1 of the 2022 Payment Notice final rule were in line with the Administration’s priorities at the time to promote private market competition and increase consumer choice. Under those policies, analysis of comprehensiveness and affordability of coverage under a section 1332 waiver focused on the nature of coverage that is made available to state residents (access to coverage), rather than on the coverage that residents actually purchase. The plans that could be offered to individuals under section 1332 waivers as codified in part 1 of the 2022 Payment Notice final rule could therefore allow for more individuals to enroll in medically underwritten plans that only offer limited benefits, which is inconsistent with the goal of E.O. 14009 to reduce barriers for expanding comprehensive affordable coverage.

In response to the proposal in the 2022 Payment Notice proposed rule, commenters raised concerns that alternative plan options (which could include medically underwritten plans) can terminate or deny coverage based on health status, which would tend to affect high-risk individuals. Commenters asserted that this possibility puts individuals with greater medical needs at risk of going without effective coverage for their health care needs. Some commenters expressed concern that the potential market effects would have a disparate impact on vulnerable populations, especially low-income consumers and those with pre-existing conditions. Additionally, these commenters expressed concern that a

disparate impact on any particular group would not necessarily cause the Departments to deny a section 1332 waiver application, even though the impact on vulnerable population groups would be taken into account.

The Departments noted that they are of the view that the current interpretation of the comprehensiveness guardrail is inconsistent with the goal of E.O. 14009 to reduce barriers for expanding comprehensive affordable coverage. The Departments also noted that they are of the view that the current interpretation of the comprehensiveness guardrail is inconsistent with the goal of E.O. 13985 to pursue a comprehensive approach to advancing equity and could create barriers to health coverage for people of color and underserved groups.

As noted in the proposed rule, the proposed changes are intended to align with the President’s instructions in E.O. 14009 and E.O. 13985 to adopt policies to strengthen the implementation of the ACA and ensure high-quality health care coverage is accessible and affordable for every American. The Departments note that they are of the view that the provisions outlined in the proposed rule would further support states providing consumers with comprehensive, high-quality health care coverage that will better protect consumers with pre-existing conditions and will help protect consumers from unexpected and expected medical needs. Further, the Departments note that the provisions outlined in the proposed rule would further the goal that consumers with pre-existing conditions, particularly racial and ethnic minorities who are 1.5 to 2.0 times more likely than whites to have major chronic diseases¹⁵⁹ and as such pre-existing conditions, maintain comprehensive coverage.

The Departments sought comment on the proposed policies and interpretations related to the comprehensiveness guardrail. The Departments noted that they are of the view that the proposed provisions would have minimal impact on both states with section 1332 waivers under development and states with approved waivers. The Departments solicited comment on the impact to stakeholders.

The following is a summary of the comments received and the Departments’ responses related to 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A), the comprehensiveness guardrail.

¹⁵⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3794652/#:~:text=more%20chronic%20diseases.,Racial%20ethnic%20minorities%20are%201.5%20to%202.0%20times%20more%20likely,seem%20to%20be%20getting%20worse.>

Comment: The Departments received a few comments specifically focused on the comprehensiveness guardrail. Several commenters supported the proposal to use EHB and Medicaid coverage as a standard of comparison for the comprehensiveness guardrail. Furthermore, these commenters supported the modifications to the rule text to evaluate this guardrail based on coverage that is provided under the waiver, not just coverage that is available. One commenter recommended adding rule text to capture that the waiver cannot decrease the number of people with coverage that satisfies EHB requirements, the number of people with coverage of any particular category of EHB, or the number of individuals with coverage that includes the services covered under the state’s Medicaid or CHIP programs. Furthermore, this commenter recommended that the rule text should reaffirm that these criteria must be met in each year of the waiver.

Response: After consideration of the comments received, the Departments are adopting the proposed policies and interpretations related to the comprehensiveness guardrail, as well as the proposed amendments to 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A). As finalized, to meet the comprehensiveness guardrail, coverage under a section 1332 waiver must be forecast to be at least as comprehensive overall for residents of the state as coverage absent the waiver. For this purpose, comprehensiveness refers to the scope of benefits provided and will be measured by the extent to which coverage meets EHB or, as appropriate, Medicaid or CHIP standards. The impact on all state residents will be considered as part of this analysis, regardless of the type of coverage they would have had absent the section 1332 waiver. As explained in this preamble, the Departments will evaluate this guardrail in each year that the section 1332 waiver would be in effect to ensure that a waiver will not decrease the number of people with coverage that satisfies EHB requirements, the number of individuals with coverage of any particular category of EHB, or the number of individuals with coverage that includes the services covered under the state’s Medicaid or CHIP programs. The Departments remain committed to approving waivers that promote health insurance coverage and health equity.

Regarding the comprehensiveness guardrail regulatory provisions, the Departments are not finalizing additional changes to the rule text at this time. The Departments are of the

view that codifying more specific requirements and guidelines in regulation is unnecessary, given the policies and interpretations already discussed in this preamble and the amendments to the comprehensiveness guardrail regulations finalized in this rule, which provide states and the Federal Government the information to reasonably evaluate whether a section 1332 waiver meets the coverage guardrail and relevant policy goals.

Comment: One commenter opposed the proposal due to concerns it would stifle a state's ability to innovate through plan design. This commenter raised concerns that as proposed, the proposal "leaves no room for plan and benefit design" and encouraged the Departments to use an "overall" standard for comprehensiveness as they do for the affordability guardrail.¹⁶⁰

Response: The proposed policies and interpretations related to the statutory guardrails require that coverage be available for a comparable number of people that is as affordable and comprehensive as coverage would have been available in the absence of the waiver. The Departments disagree that the proposed policies and interpretations of the comprehensiveness guardrail will stifle a state's ability to innovate through plan design. Under the 2019 Payment Notice final rule, states have increased flexibility to change their EHB-benchmark plan.¹⁶¹ States interested in changing their EHB-benchmark plan can do so without pursuing a section 1332 waiver, following the approach finalized in the 2019 Payment Notice final rule, or they can elect to make those changes while also pursuing a section 1332 waiver to make other changes. For example, a state could select another state's EHB-benchmark plan that was applicable for the 2017 plan year, replace one or more of categories in its EHB-benchmark plan with the same categories from another state's EHB-benchmark plan that was applicable for the 2017 plan year, or select a set of benefits that would become the state's new EHB-benchmark plan.

States could also consider increasing the generosity of an EHB-benchmark plan's benefits to address health equity. Further, the Departments are of the view that the "overall" standard incorporated in the comprehensiveness guardrail analysis, which looks at the number of residents with coverage that is at least

as comprehensive as the benchmark in all ten EHB categories, any of the ten EHB categories, and full set of services under the state's Medicaid or CHIP programs, is critical to ensure that consumers continue to have comprehensive affordable coverage under a waiver. As such, the Departments are of the view that states could consider current policy flexibilities and utilizing section 1332 waivers to innovate through plan design and benefit design.

After consideration of the comments received, the Departments are adopting the proposed policies and interpretations relating to the comprehensiveness guardrail and finalizing the proposed modifications to 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A).

b. Affordability (31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B))

The Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B) to set forth a revised interpretation of the affordability guardrail. In addition, the Departments proposed, through preamble, policies and interpretations relating to the requirements for the affordability coverage guardrail that are similar to the policies and interpretations outlined in the 2015 Guidance. Specifically, the Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B) such that to satisfy the affordability requirement, the Departments, as applicable, must determine that the section 1332 waiver would provide coverage that is at least as affordable overall for residents of the state as coverage absent the waiver.

The Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B) for the affordability guardrail as follows: To meet the affordability guardrail, health care coverage under the section 1332 waiver will be required to be forecast to be as affordable overall for state residents as coverage absent the waiver.

As proposed, the Departments' policies and interpretations related to the affordability guardrail are as follows:

Affordability refers to state residents' ability to pay for health care expenses relative to their incomes and will generally be measured by comparing each individual's expected out-of-pocket spending for health coverage and services to their incomes. Out-of-pocket spending for health care includes premiums (or equivalent costs for

enrolling in coverage), and spending such as deductibles, co-pays, and co-insurance, associated with the coverage or direct payments for health care. Spending on health care services that are not covered by a health plan or health coverage could also be taken into account if they are affected by the section 1332 waiver proposal. The impact on all state residents will be required to be considered, regardless of the type of coverage they would have had absent the section 1332 waiver. Under the proposed provisions and interpretation, this condition generally must be forecast to be met in each year that the section 1332 waiver would be in effect.

Section 1332 waivers will be evaluated not only based on how they affect affordability on average, but also on how they affect the number of individuals with large health care spending burdens relative to their incomes. Increasing the number of state residents with large health care spending burdens will cause a section 1332 waiver proposal to fail the affordability requirement, even if the waiver would increase affordability for many other state residents. Given that eligibility for comprehensive coverage among the uninsured varies across racial and ethnic groups, the Departments' assessment of whether the proposal meets the affordability requirement will also take into account the effects across different groups of state residents, and, in particular, effects on vulnerable or underserved residents, including low-income individuals, older adults, those with serious health issues or who have a greater risk of developing serious health issues, and people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.¹⁶² A section 1332 waiver will be highly unlikely to be approved by the Secretaries under the policies and interpretations set forth in the preambles to the proposed rule and this final rule if it reduces affordability for these vulnerable or underserved groups, even if the waiver would maintain affordability in the

¹⁶⁰ Oregon Department of Consumer and Business Services, the State of Oregon's insurance regulator, and the Oregon Health Authority comment letter on proposed rule.

¹⁶¹ 45 CFR 156.111.

¹⁶² These groups include individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. See <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-Federal-government/>.

aggregate. In addition, a section 1332 waiver will fail to meet the affordability guardrail if it would reduce the number of individuals with coverage that provides a minimal level of protection against excessive cost sharing. In particular, section 1332 waivers that reduce the number of people with insurance coverage that provides both an AV equal to or greater than 60 percent and an out-of-pocket maximum that complies with section 1302(c)(1) of the ACA, will fail to meet this guardrail under the policies and interpretations set forth in this rule. Section 1332 waivers that reduce the number of people with coverage that meets the affordability requirements set forth in sections 1916 and 1916A of the Act, as codified in 42 CFR part 447, subpart A, while holding the state's Medicaid policies constant will also fail under the affordability guardrail.

Consistent with 31 CFR 33.108(f) and 45 CFR 155.1308(f), the section 1332 waiver application must include analysis and supporting data that establishes that the waiver satisfies this requirement. This includes information on estimated individual out-of-pocket costs (premium and out-of-pocket expenses for deductibles, co-payments, co-insurance, co-payments and plan differences) by income, health expenses, health insurance status, and age groups, absent the section 1332 waiver and with the waiver. The expected changes in premium contributions and other out-of-pocket costs and the combined impact of changes in these components should be identified separately. The application should also describe any changes in employer contributions to health coverage or in wages expected under the section 1332 waiver. The application should identify any types of individuals for whom affordability of coverage would be reduced by the section 1332 waiver.

As discussed previously in the preamble of the proposed rule, the affordability guardrail interpretation outlined in the 2018 Guidance and codified in part 1 of the 2022 Payment Notice final rule aimed to increase consumer choice to allow states to provide access to health insurance coverage at different prices points and benefits levels. The Departments noted that they are of the view that this interpretation of the affordability guardrail is inconsistent with the goal of E.O. 14009 to reduce barriers for expanding comprehensive affordable coverage. The current interpretation could allow for more individuals, including potentially those with pre-existing conditions, to enroll in medically underwritten plans that

charge higher out-of-pocket costs, which is inconsistent with the goal of the E.O. to reduce barriers for expanding comprehensive affordable coverage. As proposed, the changes were intended to align with the President's instruction in E.O. 14009 to adopt policies to strengthen the implementation of the ACA and ensure high-quality health care is accessible and affordable for every American. The Departments noted that they are of the view that the provisions outlined in the proposed rule would further support states providing consumers with comprehensive, high-quality affordable health care coverage that will better protect consumers with pre-existing conditions, and will help protect consumers from unexpected and expected medical needs.

The Departments sought comment on these proposed policies and interpretations related to the affordability guardrail. The Departments noted that they are of the view the proposal would have minimal impact on both states with section 1332 waivers under development and states with approved waivers. The Departments solicited comment on the impact to stakeholders.

The following is a summary of the comments received and the Departments' responses related to 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B), the affordability guardrail.

Comment: Commenters were generally supportive of the proposals related to the affordability guardrail. These commenters supported the modifications to require coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of title I of the ACA. Commenters were supportive of the policies outlined in the preamble to the proposed rule, including the Departments' policy under which they would evaluate whether consumers would have large health care spending burdens relative to their incomes and will examine the effects on various vulnerable groups. Additionally, one commenter recommended that the rule text should similarly require examination of the effect of a proposed waiver on vulnerable groups and the groups now eligible for the largest premium credits and cost sharing reductions.

Response: The Departments appreciate commenters' support and are finalizing the amendments to 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B) and the affordability guardrail policies and interpretations as proposed. As

finalized, to meet the affordability guardrail, a section 1332 waiver must be forecast to be as affordable overall for state residents as coverage absent the waiver. The impact on all state residents will be considered as part of this analysis, regardless of the type of coverage they would have had absent the section 1332 waiver. Section 1332 waivers will be evaluated not only based on how they affect affordability on average, but also on how they affect the number of individuals with large health care spending burdens relative to their incomes. As previously explained, in applying this guardrail, the Departments will examine the impact the waiver has on state residents' ability to pay for health care expenses relative to their incomes and will generally measure compliance by comparing each individual's expected out-of-pocket spending for health coverage and services to their incomes. This approach allows the Departments to evaluate the affordability guardrail across various FPL levels, including for those newly eligible or eligible for expanded PTC as a result of the ARP, which impacts various FPLs differently, an issue that was raised by a commenter. Regarding the waiver's impact on the affordability of coverage for vulnerable populations, the Departments' analysis of compliance with the affordability guardrail will also take into account the effects on low-income individuals, older adults, those with serious health issues or who have a greater risk of developing serious health issues, and people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. The Departments also note that, under the proposals finalized in this rule related to the Actuarial and Economic Analysis section of the regulation,¹⁶³ states should compare comprehensiveness, affordability, coverage, and deficit neutrality with and without the section 1332 waiver. States should also include in their analysis of the aforementioned guardrails whether the proposed section 1332 waiver would increase health equity in keeping with goals of with E.O. 13985, which will provide the Departments with information to evaluate the impact on vulnerable populations.

The Departments decline to finalize additional changes to the rule text at this time. The Departments are of the view that codifying more specific requirements and guidelines in regulation is unnecessary, given the policies and interpretations already

¹⁶³ See 31 CFR 33.108(f)(4)(i)-(iii) and 45 CFR 155.1308(f)(4)(i)-(iii).

discussed in this preamble and the amendments to the affordability guardrail regulations finalized in this rule, which provide states and the Federal Government the information needed to reasonably evaluate the ability of a section 1332 waiver to meet the affordability guardrail and relevant policy goals.

The Departments remain committed to approving waivers that promote health insurance coverage and health equity and are adopting the proposed policies and interpretations relating to the affordability guardrail, as well as finalizing as proposed the modifications to 31 CFR 33.108(f)(3)(iv)(B) and 45 CFR 155.1308(f)(3)(iv)(B).

c. Coverage (31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C))

The Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) to remove the coverage guardrail interpretations codified in part 1 of the 2022 Payment Notice final rule. In addition, the Departments proposed, through preamble, policies and interpretations relating to the requirements for the coverage guardrail that are similar to the policies and interpretations outlined in the 2015 Guidance. Specifically, the Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) such that to satisfy the scope of coverage requirement, the Departments, as applicable, must determine that the section 1332 waiver would provide coverage to a comparable number of state residents under the waiver as would have coverage absent the waiver.

The Departments proposed to modify the regulations at 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) for the coverage guardrail as follows: To meet the coverage guardrail, a comparable number of state residents must be forecast to have coverage under the section 1332 waiver as would have had coverage absent the waiver.

As proposed, the Departments' policies and interpretations related to the coverage guardrail are as follows:

Coverage refers to MEC as defined in 26 U.S.C. 5000A(f). For this purpose, "comparable" means that the forecast of the number of covered individuals is no less than the forecast of the number of covered individuals absent the section 1332 waiver. This condition generally will be required to be forecast to be met in each year that the section 1332 waiver would be in effect.

The impact on all state residents will be considered, regardless of the type of

coverage they would have had absent the section 1332 waiver. For example, while a section 1332 waiver may not change the terms of a state's Medicaid coverage or change existing Medicaid demonstration authority, changes in Medicaid enrollment—whether increases or decreases—that result from a section 1332 waiver, holding the state's Medicaid policies constant, will be considered in evaluating the number of residents with coverage under a waiver.

Assessment of whether the section 1332 waiver application covers a comparable number of individuals will also take into account the effects across different groups of state residents, and, in particular, effects on vulnerable or underserved residents, including low-income individuals, older adults, those with serious health issues or who have a greater risk of developing serious health issues, and people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.¹⁶⁴ A section 1332 waiver will be highly unlikely to be approved by the Secretaries if it would reduce coverage for these populations, even if the waiver would provide coverage to a comparable number of residents in the aggregate. Finally, analysis under the coverage requirement will take into account whether the section 1332 waiver sufficiently prevents gaps in or discontinuations of coverage.

Consistent with 31 CFR 33.108(f) and 45 CFR 155.1308(f), the section 1332 waiver application must include analysis and supporting data that establishes that the waiver satisfies this requirement, including information on the number of individuals covered by income, health expenses, health insurance status, and age groups, under current law and under the waiver, including year-by-year estimates. The application should identify any types of individuals, including vulnerable and underserved individuals, who are more or less likely to be covered under the waiver than under current law.

¹⁶⁴ These groups include individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. See <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-Federal-government/>.

As discussed previously in the preamble to the proposed rule, under the interpretation outlined in the 2018 Guidance and codified in part 1 of the 2022 Payment Notice final rule, the coverage guardrail would be met if at least as many residents are enrolled in health coverage, including both comprehensive and less comprehensive health plans, as would be enrolled absent the waiver. That interpretation was intended to promote choice among a wide range of plans to ensure that consumers can enroll in coverage that is right for them. As such, the Departments noted that the interpretations set forth in the 2018 Guidance and codified in part 1 of the 2022 Payment Notice final rule permit states to provide access to less comprehensive or less affordable coverage as an additional option for their residents to choose. Under the current policy, as long as a comparable number of residents are projected to be covered as would have been covered absent the section 1332 waiver, the coverage guardrail would be met. The Departments noted that this interpretation of the coverage guardrail is inconsistent with the goal of E.O. 14009 to reduce barriers for expanding comprehensive affordable coverage. The interpretation could allow for more individuals to enroll in medically underwritten plans that offer limited benefits, charge higher out-of-pocket costs, or both, which is inconsistent with the goal of E.O. 14009 to reduce barriers for expanding comprehensive, high-quality, affordable coverage. As discussed in the preamble to the proposed rule, the proposed provisions are intended to align with the President's instruction in E.O. 14009 to adopt policies to strengthen the implementation of the ACA and ensure high-quality health care is accessible and affordable for every American. The Departments are of the view that the proposals outlined in the proposed rule will further support states providing consumers with comprehensive, high-quality affordable health care that will better protect consumers with pre-existing conditions and will help protect consumers from unexpected and expected medical costs.

The Departments sought comment on the proposed policies and interpretations related to the coverage guardrail. The Departments are of the view that the proposed provisions would have minimal impact on both states with section 1332 waivers under development and states with approved waivers. The Departments solicited comment on the impact to stakeholders.

The following is a summary of the comments received and the

Departments' responses related to 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C), the coverage guardrail.

Comment: Commenters were generally supportive of the proposals related to the coverage guardrail. One commenter recommended that the regulatory language be clarified to indicate that the coverage it references is comprehensive coverage, meeting the standards set forth in 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A).

Response: The Departments appreciate commenters' support and are adopting the policies and interpretations related to the coverage guardrail policy and finalizing the amendments to 31 CFR 33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) as proposed. The Departments confirm that for purposes of the coverage guardrail, the term "coverage" refers to minimum essential coverage as defined in 26 U.S.C. 5000A(f), which aligns with the policies and interpretations described in this preamble for the comprehensiveness guardrail analysis under 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A). As explained in this preamble, the Departments will evaluate waiver proposals against this guardrail to ensure that, under the waiver, a comparable number of state residents are forecast to have coverage under the section 1332 waiver as would have had coverage absent the waiver. The impact on all state residents will be considered, regardless of the type of coverage they would have had absent the section 1332 waiver. The Departments remain committed to approving waivers that promote health insurance coverage and health equity.

Regarding the coverage guardrail regulations, the Departments are not finalizing additional changes to the rule text at this time. The Departments are of the view that codifying more specific requirements and guidelines in regulation is unnecessary, given the policies and interpretations already discussed in this preamble and the amendments to the coverage guardrail regulations finalized in this rule, which provide states and the Federal Government the information necessary to reasonably evaluate the ability of a section 1332 waiver to meet the coverage guardrail and relevant policy goals.

After consideration of the comments received, the Departments are adopting the policies and interpretations related to the coverage guardrail and finalizing the modifications to 31 CFR

33.108(f)(3)(iv)(C) and 45 CFR 155.1308(f)(3)(iv)(C) as proposed.

d. Deficit Neutrality (31 CFR 33.108(f)(3)(iv)(D) and 45 CFR 155.1308(f)(3)(iv)(D))

The Departments did not propose to modify the regulations at 31 CFR 33.108(f)(3)(iv)(D) and 45 CFR 155.1308(f)(3)(iv)(D) for the deficit neutrality guardrail, but proposed, through preamble, policies and interpretations relating to the requirements for the deficit neutrality guardrail consistent with the policies outlined in the 2015 and 2018 Guidance. As proposed, the Departments' policies and interpretations related to the deficit neutrality guardrail are as follows:

Under the deficit neutrality guardrail, the projected Federal spending net of Federal revenues under the section 1332 waiver is required to be equal to or lower than projected Federal spending net of Federal revenues in the absence of the waiver.

The estimated effect on Federal revenue is required to include all changes in income, payroll, or excise tax revenue, as well as any other forms of revenue (including user fees), that would result from the proposed section 1332 waiver. Estimated effects include, for example, changes in the amounts the Federal Government pays in PTC, small business tax credits, or other health coverage tax credits; changes in the amount of employer shared responsibility payments and excise taxes on high-cost employer-sponsored plans collected by the Federal Government; and changes in income and payroll taxes resulting from changes in tax exclusions for employer-sponsored insurance and in deductions for medical expenses.

The effect on Federal spending includes all changes in Federal financial assistance (PTC, small business tax credits, and CSRs) and other direct spending, such as changes in Medicaid spending (while holding the state's Medicaid policies constant) that would result from the changes made through the proposed section 1332 waiver. Projected Federal spending under the section 1332 waiver proposal also includes all administrative costs to the Federal Government, including any changes in IRS administrative costs, Federal Exchange administrative costs, and other administrative costs associated with the waiver or alleviated by the waiver.

Under the policies and interpretations outlined in the proposed rule, section 1332 waivers must not increase the Federal deficit over the period of the

waiver (which may not exceed 5 years unless renewed) or in total over the 10-year budget plan submitted by the state as part of the section 1332 waiver application. Consistent with the policies in the 2015 Guidance and in the 2018 Guidance, the 10-year budget plan would be required to describe, for both the period of the waiver and for the 10-year budget window, the projected Federal spending and changes in Federal revenues under the section 1332 waiver and the projected Federal spending and changes in Federal revenues in the absence of the waiver for each year of the 10 years.

The 10-year budget plan should assume the section 1332 waiver would continue permanently, but should not include Federal spending or savings attributable to any period outside of the 10-year budget window. A variety of factors, including the likelihood and accuracy of projected spending and revenue effects and the timing of these effects, will be considered when evaluating the effect of the section 1332 waiver on the Federal deficit. A section 1332 waiver that increases the deficit in any given year is less likely to meet the deficit neutrality requirement than one that does not.

The Departments note that the approach outlined in part 1 of the 2022 Payment Notice final rule for the deficit neutrality guardrail is consistent with E.O. 14009 as it would not reduce coverage or otherwise undermine the ACA and Medicaid.

The Departments sought comment on the proposed policies and interpretations related to the deficit neutrality guardrail. The Departments noted that the proposal would have minimal impact on both states with section 1332 waivers under development and states with approved waivers. The Departments solicited comment on the impact to stakeholders.

The following is a summary of the comments received and the Departments' responses related to 31 CFR 33.108(f)(3)(iv)(D) and 45 CFR 155.1308(f)(3)(iv)(D), the deficit neutrality guardrail. The summary of comments and the Departments' responses that follow also address comments regarding pass-through funding that were made in connection with the Departments' proposals related to the deficit neutrality guardrail.

Comment: The Departments received two specific comments that were generally supportive of the proposals related to the deficit neutrality guardrail. One commenter noted that the "Departments' longstanding approach . . . appropriately carries out this statutory requirement by specifying

that the Federal Government's projected spending net of revenues under a section 1332 waiver would need to be equal to or lower than would occur in the absence of a waiver."¹⁶⁵ Another commenter noted that while it supports the policies and interpretation of the deficit neutrality guardrail, "the Departments should calculate pass-through funding differently and in a way that would allow states to share more of the Federal savings that a section 1332 waiver could generate."

Response: The Departments appreciate commenters' support and are finalizing the policies and interpretations related to the deficit neutrality guardrail policy as proposed. Regarding pass-through funding, states with approved section 1332 waivers may only receive pass-through funding associated with resulting reductions in Federal spending on certain types of Federal financial assistance specified in the statute and reduced, as necessary, to ensure deficit neutrality, as required by the statute.¹⁶⁶

Comment: The Departments received several comments requesting that the Departments revisit their proposed policies and interpretations of the deficit neutrality guardrail. These commenters expressed concern that as proposed, the policies and interpretations are overly strict and narrow, which may prevent states from pursuing innovative new models that would expand coverage, and are inconsistent with the original intent of the waiver program and the Administration's goal of increasing enrollment in comprehensive coverage. Furthermore, these commenters contended that the Departments' overall proposed interpretation of deficit neutrality is inconsistent with the other statutory guardrails and the ACA more broadly. Other commenters were of the view that these policies and interpretations were also contrary to E.O. 14009 and E.O. 13985 and should be updated to explicitly allow state efforts to experiment with improving on the ACA while reducing racial disparities due to a lack of coverage or barriers to affordability.

These commenters expressed concern that the proposed policies and interpretations of the deficit neutrality guardrail could result in a scenario where a state that pursues a section 1332 waiver that successfully results in

an increase in ACA-eligible enrollment would fail to meet the deficit neutrality requirement because the increase in enrollment would increase Federal spending on PTC, thereby increasing the Federal deficit. The commenters stated that this creates a disincentive for states to pursue innovative health care reform under a section 1332 waiver, since, if a state were to pursue an innovative health care proposal outside the section 1332 process which resulted in increased enrollment, the Federal Government would bear the cost of any increased enrollment. Further, commenters noted that the Departments' overall interpretation of the deficit neutrality guardrail is contrary to the goals of the ACA and E.O.s 14009 and 13985 as people who are eligible but not enrolled are disproportionately from communities of color. As such, commenters contended that the policies and interpretations as proposed would penalize states seeking to innovate through a section 1332 waiver and contradict the Departments' stated goal to expand coverage.

The commenters recommended that the Departments instead consider three alternative ways to evaluate the deficit neutrality guardrail. One recommendation is that the Departments take into account those who are currently eligible for coverage, but unenrolled, in the baseline coverage for evaluating the deficit neutrality guardrail and costs used to compute pass-through funding. Commenters noted that this alternate interpretation of "deficit neutrality" aligns with the aims of the ACA to expand coverage and would grant states the flexibility to create new waiver designs, including a state-level public option, to meet those goals. Commenters noted utilizing this approach for section 1332 waivers would align with the statutory interpretation for section 1115 demonstrations and Medicaid waivers that a law should be interpreted to promote rather than undermine the accomplishment of its core objectives. Further, the commenters noted that CMS has permitted states to juxtapose waiver spending against baselines reflecting state implementation of alternative policies permitted without any waiver in the context of section 1115 demonstrations to promote statutory objectives and increased enrollment of eligible people.

Another commenter recommended that instead of looking at deficit neutrality on an annual basis for each and every year of the waiver, the Departments should instead consider the deficit neutrality guardrail over a 10-year period to allow states greater

opportunity for innovation, such as creating a public option. The commenter noted that this approach would be consistent with existing requirements for section 1332 waivers to include a 10-year budget projection in 1332 waiver applications. In other rulemaking, commenters have also noted that this approach would be consistent with how the Congressional Budget Office (CBO) scores are generally analyzed for deficit neutrality over a 10-year period.

Another recommendation from commenters was that the Departments evaluate deficit neutrality and compute pass-through funding on a per capita basis. These commenters explained that a per capita basis would provide a sustainable funding source in the event future enrollment exceeds current levels. These commenters further noted that under section 1115 demonstration projects, the calculation of the without waiver budget neutrality expenditure limit(s) is based on spending per eligible individual, per month (PMPM). Using this PMPM approach, the commenters explained that the state is not at risk for increased costs associated with increases in enrollment, and does not accrue savings from decreases in enrollment. Unexpected increases in enrollment could be a consequence of factors outside the demonstration and beyond the state's complete control—such as changing economic conditions and natural disasters. The state is at risk only for increases to the PMPM cost growth—not for the increases in enrollment.¹⁶⁷

Response: The Departments appreciate these commenters' recommendations and acknowledge stakeholders' interest in pursuing innovative strategies to increase enrollment. After consideration of the comments received, the Departments are finalizing as proposed their interpretation of the requirement that waivers must not increase the Federal deficit.¹⁶⁸ Thus, the projected Federal spending net of Federal revenues under the section 1332 waiver is required to be equal to or lower than projected Federal spending net of Federal revenues in the absence of the waiver to meet the deficit neutrality guardrail requirement. The Departments also clarify that the evaluation of whether a section 1332 waiver increases the Federal deficit will include consideration of the projected impact of the waiver over the period of

¹⁶⁵ Center on Budget and Policy Priorities comment letter on proposed rule.

¹⁶⁶ See section 1332(a)(3) of the ACA, which refers to premium tax credits, cost-sharing reductions, and small business credits under section 36B of the Code or under Part I of subtitle E of the ACA.

¹⁶⁷ SMD # 18–009 RE: Budget Neutrality Policies for Section 1115(a) Medicaid Demonstration Projects available online at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18009.pdf>.

¹⁶⁸ See section 1332(b)(1)(D) of the ACA.

the waiver (which may not exceed 5 years unless renewed) and over the 10-year budget plan. However, the Departments reiterate that under the policies and interpretations finalized in this rule, a section 1332 waiver that increases the Federal deficit in any given year is less likely to meet this guardrail than one that does not.

The Departments appreciate commenters' suggestions on the deficit neutrality guardrail, as well as suggestions related to the affordability, comprehensiveness, and coverage guardrails and pass-through funding. The Departments reaffirm their aim to promote health equity and increase health insurance coverage through section 1332 waivers and are of the view that the proposed policies and interpretations related to the deficit neutrality guardrail are consistent with the goals of the ACA, and align with E.O. 14009 and E.O. 13985, as states are still encouraged to consider ways to experiment with improving coverage and affordability for vulnerable populations. Thus, after consideration of the comments received, the Departments are adopting the proposed policies and interpretations related to the deficit neutrality guardrail. The Departments are also finalizing the accompanying pass-through funding policies and interpretations, as well as the codification of 31 CFR 33.122 and 45 CFR 155.1322, as proposed.

4. Section 1332 Application Procedures (31 CFR 33.108(f)(4) and 45 CFR 155.1308(f)(4))

a. Actuarial and Economic Analysis (31 CFR 33.108(f)(4)(i)–(iii) and 45 CFR 155.1308(f)(4)(i)–(iii))

As required under 31 CFR 33.108(f)(4)(i)–(iii) and 45 CFR 155.1308(f)(4)(i)–(iii), states must include actuarial analyses and actuarial certifications, economic analyses, and the data and assumptions used to demonstrate and support the state's estimates that the proposed section 1332 waiver will comply with the statutory guardrails. The Departments did not propose any regulatory changes to 31 CFR 33.108(f)(4)(i)–(iii) and 45 CFR 155.1308(f)(4)(i)–(iii), but did propose, through preamble, policies relating to the requirements for the actuarial and economic analyses that are similar to the policies outlined in the 2015 and 2018 Guidance. The Departments proposed these policies to help ensure that the Departments have the appropriate and necessary information to measure the impact of waivers on the guardrails, particularly related to coverage. This information is especially

important in light of the goal of E.O. 14009 to provide more comprehensive affordable coverage to consumers. In addition, the Departments encouraged states to include in their analysis whether the proposed section 1332 waiver would increase health equity in line with E.O. 13985. As proposed, the policies are as follows:

Consistent with the 2015 and 2018 Guidance, the determination of whether a proposed section 1332 waiver meets the requirements under section 1332 and the calculation of the pass-through funding amount will be made using generally accepted actuarial and economic analytic methods, such as micro-simulation. The analysis will rely on assumptions and methodologies that are similar to those used to produce the baseline and policy projections included in the most recent President's Budget (or Mid-Session Review), but adapted as appropriate to reflect state-specific conditions. As provided in 31 CFR 33.108(f)(4)(i) and 45 CFR 155.1308(f)(4)(i), the state must include actuarial analyses and actuarial certifications to support the state's estimates that the proposed section 1332 waiver will comply with the comprehensive coverage requirement, the affordability requirement, and the scope of coverage requirement. Consistent with the 2018 Guidance, these actuarial analyses and certifications should be conducted by a member of the American Academy of Actuaries.

The Departments' analysis of whether a proposed section 1332 waiver meets the requirements under section 1332 will be based on state-specific estimates of the current level and distribution of population by the relevant economic and demographic characteristics, consistent with the 2015 and 2018 Guidance, including income and source of health coverage. It will generally use Federal estimates of population growth, and economic growth as published in the Analytical Perspectives volume released as part of the President's Budget¹⁶⁹ and health care cost growth¹⁷⁰ to project the initial state variables through the 10-year budget plan window. However, in limited circumstances where it is expected that a state will experience substantially different trends than the nation as a whole in the absence of a section 1332 waiver, the Secretaries may determine

that state-specific assumptions will be used.

Consistent with the 2018 Guidance and largely similar to the 2015 Guidance, estimates of the effect of the section 1332 waiver will assume, in accordance with standard estimating conventions, that macroeconomic variables like population, output, and labor supply are not affected by the waiver. However, estimates will take into account, as appropriate, other changes in the behavior of individuals, employers, and other relevant entities induced by the section 1332 waiver where applicable, including employer decisions regarding what coverage (and other compensation) they offer and individual decisions regarding whether to take up coverage. The same state-specific and Federal data, assumptions, and model are used to calculate comprehensiveness, affordability, and coverage, and relevant state components of Federal taxes and spending under the section 1332 waiver and under current law.

The analysis and information submitted by the state as part of the section 1332 waiver application must conform to these standards. Consistent with the 2015 and 2018 Guidance, the application would describe all modeling assumptions used, sources of state-specific data, and the rationale for any deviation from Federal forecasts. A state may be required under 31 CFR 33.108(f)(4)(vii) and 45 CFR 155.1308(f)(4)(vii) to provide to the Secretaries copies of any data used for their section 1332 waiver analyses that are not publicly available so that the Secretaries can independently verify the analysis produced by the state.

Consistent with the 2018 Guidance, for each of the guardrails, the state must clearly explain its estimates with and without the section 1332 waiver. The actuarial and economic analyses would be required to compare comprehensiveness, affordability, coverage, and deficit neutrality with and without the section 1332 waiver. The deficit neutrality analysis will specifically examine net Federal spending and revenues under the section 1332 waiver to those measures absent the waiver (the baseline) for each year of the waiver. If the state is submitting a section 1332 waiver application for less than a 5-year period, the actuarial analysis could be submitted for the period of the waiver. The Departments, in accordance with their regulations,¹⁷¹ could request

¹⁶⁹ https://www.whitehouse.gov/omb/budget/Analytical_Perspectives.

¹⁷⁰ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html?redirect=/NationalHealthExpendData/>.

¹⁷¹ See 31 CFR 33.108(g) and 45 CFR 155.1308(g).

additional information or data in order to conduct their assessments.

The state should also provide a description of the models used to produce these estimates, including data sources and quality of the data, key assumptions, and parameters for the section 1332 waiver. Consistent with the 2018 Guidance, the Departments will not prescribe any particular method of actuarial analysis to estimate the potential impact of a section 1332 waiver. However, the state should explain its modeling in sufficient detail to allow the Secretaries to evaluate the accuracy of the state's modeling and the comprehensiveness and affordability of the coverage available under the state's section 1332 waiver proposal. As permitted under 31 CFR 33.108(g) and 45 CFR 155.1308(g) the state may be required to provide, upon request by the Secretaries, data or other information that it used to make its estimates, including an explanation of the assumptions used in the actuarial analysis.

The Departments sought comment on the proposals, and did not receive any comments in response to these proposals regarding 31 CFR 33.108(f)(4)(i)–(iii) and 45 CFR 155.1308(f)(4)(i)–(iii). The Departments are finalizing these policies as proposed.

b. Implementation Timeline and Operational Considerations (31 CFR 33.108(f)(4)(iv) and 45 CFR 155.1308(f)(4)(iv))

As required under 31 CFR 33.108(f)(4)(iv) and 45 CFR 155.1308(f)(4)(iv), states must include in their applications for initial approval of a section 1332 waiver a detailed draft timeline for the state's implementation of the proposed waiver. The Departments did not propose any regulatory changes to 31 CFR 33.108(f)(4)(iv) and 45 CFR 155.1308(f)(4)(iv). Rather, the Departments proposed the operational considerations in preamble that states should take into account when developing a waiver application, waiver plan, and implementation timeline. Specifically, the Departments proposed these operational considerations to provide additional information regarding how HHS and the IRS may be able to support a state in implementing a section 1332 waiver plan so states can take this information into consideration as it relates to their implementation timelines. The Departments noted that the proposals would help to ensure that the Departments have the appropriate and necessary information to measure the impact of proposed waivers on the statutory guardrails, particularly related

to coverage. This information is especially important in light of the goal of E.O. 14009 to provide more comprehensive affordable coverage to consumers. In addition, the Departments encouraged states to include in their analysis whether the proposed section 1332 waiver would increase health equity in line with E.O. 13985. Upon consideration, the approach proposed with regard to operational considerations was revised from the 2018 Guidance with regard to the use of the Exchange information technology platform (the Federal platform) and IRS operational considerations to maintain smooth operations of the Exchanges consistent with E.O. 14009 and this Administration's goals to protect and strengthen Medicaid and the ACA and to make high-quality health care accessible and affordable for every American. A discussion of operational considerations for waivers that use the Federal platform for FFE states and IRS functionality follows, as well as comments on the proposals.

i. Use of Federal Platform Technology

HHS operates the Federal platform utilized by FFEs and by some State Exchanges for eligibility and enrollment functions. For technical, operational, and fiscal efficiency, the Federal platform is generally designed to support uniform administration across the states that utilize it. With that noted, HHS would be open to inquiries and further discussion with states that are developing section 1332 waiver proposals and are interested in potential technical collaboration. For example, over the past few years HHS has offered assistance to states implementing state-based reinsurance programs.¹⁷² Currently, states can request that the Federal Government assist with the calculation of issuers' eligible state reinsurance payments based on the state reinsurance parameters as part of the state's approved section 1332 waiver plan. Under this arrangement, states are still responsible for making reinsurance payments to issuers and otherwise administering and overseeing their programs.

The Departments noted that states that are interested in this assistance should notify HHS early in the process about the state's interest and the state's parameters (that is, claims cost-based, conditions-based, or other) for HHS to assess the feasibility of providing this

support. Should a final proposal involve any customized or specialized Federal technical or operational capabilities, the Departments noted that states would be responsible for funding the development and operation of these capabilities under the Intergovernmental Cooperation Act (ICA).¹⁷³ Under the ICA, a Federal agency generally may provide certain technical and specialized services to state governments, so long as the state covers the full costs of those services. Accordingly, where a state intends to rely on HHS for technical services related to its section 1332 waiver proposal, the state would be required to cover HHS's costs. For example, states implementing state-based reinsurance programs that request technical or specialized services from HHS with respect to calculating state reinsurance payments are responsible for the Federal costs associated with providing this service, including development, implementation, maintenance, operations, and customer support. For this reason, the Departments noted that should HHS and a state agree to such technical or specialized services to support an approved section 1332 waiver plan, the Departments would not consider costs for HHS services covered under the ICA as an increase in Federal spending resulting from the state's waiver plan for purposes of the deficit neutrality analysis.

As outlined in the preamble of the proposed rule for the deficit neutrality guardrail, costs associated with changes to Federal administrative processes that are not covered under the ICA would be taken into account in determining whether a waiver application satisfies the deficit neutrality requirement. Regulations at 31 CFR 33.108(f)(4) and 45 CFR 155.1308(f)(4) require that such costs be included in the 10-year budget plan submitted by the state. As specific section 1332 waiver proposals are submitted, the Departments noted that HHS would work closely with states to determine which Federal costs are covered under the ICA (and thus are not subject to deficit neutrality guardrail), and which are not covered under the ICA (and thus are subject to the deficit neutrality guardrail).

ii. IRS Functionality

Certain changes that affect IRS administrative processes may make a section 1332 waiver proposal infeasible for the Departments to accommodate. The IRS generally is not able to administer different sets of Federal tax rules for different states. As a result, the

¹⁷² For plan year 2021, HHS is providing this support for six states: Colorado, Delaware, Maryland, New Hampshire, North Dakota, and Pennsylvania.

¹⁷³ Public Law 90–577.

Departments noted that while a state may propose to entirely waive the application of one or more of the Federal tax provisions listed in section 1332 for taxpayers in the state, it would generally not be feasible to design a section 1332 waiver that would require the IRS to administer a program that alters these provisions for taxpayers in the state.

The Departments noted that in some limited circumstances, the IRS may be able to accommodate small adjustments to the existing systems for administering Federal tax provisions. However, the Departments noted that it is generally not feasible to have the IRS administer a different set of PTC eligibility or PTC computation rules for individuals in a particular state. Thus, states contemplating a waiver proposal that includes a modified version of a Federal tax provision could consider waiving the provision entirely and creating a subsidy program administered by the state as part of a section 1332 waiver proposal.

In addition, a section 1332 waiver proposal that partly or completely waives one or more Federal tax provisions in a state may create administrative costs for the IRS. As noted in the preamble for the deficit neutrality guardrail of the proposed rule, costs associated with changes to Federal administrative processes would be taken into account in determining whether a waiver application satisfies the deficit neutrality requirement. Regulations at 31 CFR 33.108(f)(4) and 45 CFR 155.1308(f)(4) require that such costs be included in the 10-year budget plan submitted by the state. States contemplating to waive any part of a Federal tax provision should engage with the Departments early in the section 1332 waiver application process to assess whether the waiver proposal is feasible for the IRS to implement, and, if applicable, to assess the administrative costs to the IRS of implementing the waiver proposal.

The Departments did not receive any public comments in response to these proposals regarding 31 CFR 33.108(f)(4)(iv) and 45 CFR 155.1308(f)(4)(iv), Implementation Timeline and Operational Considerations, and are finalizing these policy clarifications and operational considerations as proposed.

5. Public Input on Waiver Proposals (31 CFR 33.112 and 45 CFR 155.1312)

Section 1332(a)(4)(B)(i) of the ACA, and regulations at 31 CFR 33.112 and 45 CFR 155.1312, require states to provide a public notice and comment period for a section 1332 waiver application

sufficient to ensure a meaningful level of public input prior to submitting an application. Under the current requirements, as part of the state's public notice and comment period, a state with one or more federally-recognized tribes must conduct a separate process for meaningful consultation with such tribes.¹⁷⁴ In addition, a state must make available, at the beginning of its public notice and comment period, through its website or other effective means of communication, a public notice that includes all of the information outlined in 31 CFR 33.112(b) and 45 CFR 155.1312(b). The state must also update this information, as appropriate. After issuance of this notice and prior to submission of a new section 1332 waiver application, the state must conduct public hearings and provide interested parties an opportunity to learn about and comment on the contents of the state's section 1332 waiver application.¹⁷⁵ Because section 1332 waiver applications may vary significantly in their complexity and breadth, the regulations provide states with flexibility in determining the length of the comment period required to allow for meaningful and robust public engagement. Consistent with Federal civil rights law, including section 1557 of the ACA, section 504 of the Rehabilitation Act of 1973, and title II of the Americans with Disabilities Act, section 1332 waiver applications must be posted online in a manner that is accessible to individuals with disabilities. To assist with ensuring website accessibility, states may look to national standards issued by the Architectural and Transportation Barriers Compliance Board (often referred to as "section 508 standards"),¹⁷⁶ or alternatively, the World Wide Web Consortium's Web Content Accessibility Guidelines (WCAG)¹⁷⁷ 2.0 Level AA standards.

While the Departments did not propose any regulatory changes to 31 CFR 33.112 and 45 CFR 155.1312, through the preamble, the Departments proposed policies and interpretations for the state public notice requirements. More specifically, the Departments proposed to maintain the current standard that the state comment period

for a section 1332 waiver application should generally be no less than 30 days.¹⁷⁸ The Departments explained that a general standard requiring a minimum 30-day comment period would be sufficient to allow for meaningful and robust public engagement on a state's waiver application and reiterated that a longer period may be appropriate for complex proposed waiver plans.

Section 1332(a)(4)(B)(iii) of the ACA and its implementing regulations¹⁷⁹ also require the Federal Government to provide a public notice and comment period once the Secretaries receive an application. The period must be sufficient to ensure a meaningful level of public input and must not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedure Act, or requirements that are unreasonable or unnecessarily burdensome with respect to state compliance.¹⁸⁰ Under existing regulations, 31 CFR 33.108(f) and 45 CFR 155.1308(f), a submitted section 1332 waiver application will not be deemed received until the Secretaries have made the preliminary determination that the application is complete. As with the state comment period described earlier, the Departments did not propose regulatory amendments and instead proposed adoption of policies and interpretations related to the Federal comment period. More specifically, the Departments explained that the length of the Federal comment period should also reflect the complexity of the section 1332 waiver proposal and similarly proposed that the Federal comment period should also generally not be less than 30 days.¹⁸¹

¹⁷⁸ Notwithstanding this policy, the Departments clarified that states with approved waivers and states seeking approval for proposed waivers continue to have flexibility to submit requests to the Departments to modify certain public participation requirements during the COVID-19 PHE. See 31 CFR 33.118 and 45 CFR 155.1318. Also see the November 2020 IFC, 85 FR 71142. As detailed below, in this rulemaking, the Departments are finalizing the proposal to extend similar flexibilities during future emergent situations. As such, states with approved waivers and state seeking approval for proposed waivers will have similar flexibilities to submit requests to the Departments to modify certain public participation requirements during future emergent situations.

¹⁷⁹ See 31 CFR 33.116 and 45 CFR 155.1316.

¹⁸⁰ See section 1332(a)(4)(B)(iii) of the ACA, 31 CFR 33.116(b) and 45 CFR 155.1316(b).

¹⁸¹ Notwithstanding this policy, the Departments clarified that states with approved waivers and states seeking approval for proposed waivers continue to have flexibility to submit requests to the Departments to modify certain public participation requirements during the COVID-19 PHE. See 31 CFR 33.118 and 45 CFR 155.1318. Also see the November 2020 IFC, 85 FR 71142. As detailed below, in this rulemaking, the Departments are

¹⁷⁴ See 31 CFR 33.112(a)(2) and 45 CFR 155.1312(a)(2).

¹⁷⁵ See 31 CFR 33.112(c) and 45 CFR 155.1312(c).

¹⁷⁶ For more information on section 508 standards, see: <https://section508.gov/manage/program-roadmap>. See also: <https://www.hhs.gov/sites/default/files/ocr-guidance-electronic-information-technology.pdf>.

¹⁷⁷ For more information, see the WCAG website at <http://www.w3.org/TR/WCAG20/>.

The Departments did not receive any public comments on the proposals related to 31 CFR 33.112 and 45 CFR 155.1312, Public Input on Waiver Proposals, and are finalizing these policy clarifications and interpretations as proposed.

6. Modification From the Normal Public Notice Requirements (31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR 155.1320)

In the November 2020 IFC,¹⁸² the Departments revised regulations to set forth flexibilities in the public notice requirements and post award public participation requirements for waivers under section 1332 during the COVID-19 PHE. The Departments proposed to extend these changes beyond the COVID-19 PHE to allow similar flexibilities in the event of future natural disasters; PHEs; or other emergent situations that threaten consumers' access to health insurance coverage, consumers' access to health care, or human life. The Departments proposed to consider a situation to be "emergent" if it is both unforeseen and urgent. The Departments did not propose any changes with respect to the flexibility made available in the November 2020 IFC during the COVID-19 PHE. The Departments further clarified that states with approved section 1332 waivers and states seeking approval for proposed waivers will continue to have flexibility to submit requests to the Departments to modify certain public participation requirements during the COVID-19 PHE.¹⁸³

The Departments also explained in the 2022 Payment Notice proposed rule¹⁸⁴ that CMS similarly proposed an extension of COVID-19 policy flexibilities, specifically the calculation of plan average premium and state average premium requirements for extending future premium credits ("temporary premium credits"), which was originally published in the November 2020 IFC.¹⁸⁵ In part 2 of the 2022 Payment Notice final rule, HHS finalized these policies to extend

finalizing the proposal to extend similar flexibilities during future emergent situations. As such, states with approved waivers and state seeking approval for proposed waivers will have similar flexibilities to submit requests to the Departments to modify certain public participation requirements during future emergent situations.

¹⁸² 85 FR 71142. See <https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency>.

¹⁸³ See 85 FR 71142.

¹⁸⁴ See 85 FR at 78597–78598 and 78608–78609.

¹⁸⁵ 85 FR 54820.

beyond the COVID-19 PHE, to be available, if permitted by HHS, during a future declared PHE.¹⁸⁶ In developing the policies in the proposed rule, the Departments considered extending the section 1332 flexibilities adopted in the November 2020 IFC only to future declared PHEs, but are of the view that these flexibilities, as proposed to be available on a broader basis in different times of emergent situations, would allow states to use or modify their waivers to respond to state or local emergent situations that may not rise to the level of a national declared PHE. The Departments further explained they are of the view that this best aligns with the overall statutory purpose and goals for section 1332 waivers, which are meant to allow states to craft their own unique solutions to respond to the specific health care needs in their respective markets. If the Departments were to limit these flexibilities only to future declared national PHEs, states may not be able to utilize or modify their section 1332 waivers as a tool to address state or local emergent situations or state designated emergencies which may similarly threaten consumers' access to health insurance coverage, consumers' access to health care, or human life.

In addition, the flexibilities outlined in the proposed rule are similar to those available under section 1115 demonstrations. Existing regulations at 42 CFR 431.416(g), relating to demonstration projects under section 1115 of the Act, provide that CMS may waive, in whole or in part, the state and Federal public notice requirements to expedite a decision on a proposed section 1115 demonstration application or section 1115 demonstration extension request that addresses a natural disaster, PHE, or other sudden emergency threat to human life, under certain circumstances described in the regulation. The Departments explained they are of the view that using a similar standard for section 1332 waivers would provide states the necessary flexibility to enable them to quickly respond to various emergent situations. For example, some states have used flexibilities for section 1115 demonstrations in emergent situations to address threats to human life such as mudslides and wildfires that were state-designated emergencies.

The Secretaries value the importance of the public input process, but also intend to propose to provide reprieve from certain requirements, where appropriate, in emergent situations. Allowing the Secretaries to modify the

¹⁸⁶ 86 FR at 24182–24183 and 24202–24203.

public notice and post award requirements would allow states to seek emergency relief in support of the development of quick and innovative ways to ensure consumers across the country have access to health care coverage in the face of unforeseen threats to that coverage. As was noted in the November 2020 IFC and the proposed rule, HHS and the Department of the Treasury are concerned that past trends that threaten the stability of the individual market risk pool may return, leading some issuers to cease offering coverage on the Exchanges in some states and counties and leading other issuers to increase their rates, leaving some geographic areas with limited or no affordable Exchange coverage options. Permitting the Secretaries to modify the public notice procedures, in part, will help states seeking section 1332 waivers to address such circumstances more quickly and develop innovative ways to ensure consumers have access to affordable health care coverage. Specifically, the Departments proposed to modify 31 CFR 33.118 and 45 CFR 155.1318 to broaden the Secretaries' authority to modify, in part, the otherwise applicable public notice procedures to expedite a decision on a proposed section 1332 waiver request that is submitted or would otherwise become due during emergent situations, when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. The proposed amendments to these regulations further clarify that these proposed flexibilities would be available in future natural disasters; PHEs; and other emergent situations that threaten consumers' access to health insurance coverage, consumers' access to health care, or human life, rather than being limited to only the duration of the COVID-19 PHE.

The Departments also proposed to modify 31 CFR 33.120(c)(2) and 45 CFR 155.1320(c)(2) to provide the Secretaries with similar authority to modify, in part, otherwise applicable post award public notice requirements for an approved waiver outlined in 31 CFR 33.120(c) and 45 CFR 155.1320(c) when the application of the post-award public notice procedures would be contrary to the interests of consumers during a natural disaster; PHE; or other emergent situations that threaten consumers' access to health insurance coverage, consumers' access to health care, or human life, rather than limiting this flexibility only to the duration of the COVID-19 PHE. These proposals would expand on policies published in

the November 2020 IFC that are limited to the COVID-19 PHE.

a. Public Notice Procedures and Approval (31 CFR 33.118 and 45 CFR 155.1318)

Section 1332(a)(4)(B) of the ACA provides that the Secretaries shall issue regulations providing a process for public notice and comment at the state level, including public hearings, and a process for providing public notice and comment at the Federal level after the section 1332 waiver application is received by the Secretaries, that are both sufficient to ensure a meaningful level of public input. Current regulations at 31 CFR 33.112 and 45 CFR 155.1312 specify state public notice and participation requirements for proposed section 1332 waiver requests, and 31 CFR 33.116(b) and 45 CFR 155.1316(b) specify the public notice and comment period requirements under the accompanying Federal process.

As explained in the November 2020 IFC, the Departments recognize that the current section 1332 waiver regulations regarding state and Federal public notice procedures and comment period requirements may impose barriers for states pursuing a proposed waiver request during an emergent situation, such as the COVID-19 PHE or a future natural disaster; PHE; or other emergent situation that threatens consumers' access to health insurance coverage, consumers' access to health care, or human life. It is the mission of the Departments to enhance and protect the health and well-being of all Americans. As such, the Departments proposed to extend the existing flexibilities codified in regulations to protect public health and access to health insurance coverage and care during the COVID-19 PHE to also apply in the event of a future emergent situation, such as a natural disaster; a PHE; or other emergent situations that threaten consumers' access to health insurance coverage, consumers' access to health care, or human life. These flexibilities have been important during the COVID-19 PHE and support efforts to prevent the spread of COVID-19 by limiting the need for in-person gatherings related to section 1332 waivers during the PHE. Extending these flexibilities beyond the COVID-19 PHE to future emergent situations is important to similarly help states as they may face uncertainty as to whether their waiver request will be approved in time, given the otherwise applicable state and Federal public notice procedures or public participation requirements, to expeditiously reform their health insurance markets and to protect

consumers during a future emergent situation. Some states may not consider more robust changes because they are concerned that the current section 1332 waiver application requirements are too time-consuming or burdensome to pursue during a future emergency or other emergent situation. Therefore, the Departments explained they are of the view that providing similar flexibility to modify certain public notice procedures and participation requirements during a future emergent situation will protect public health and health insurance markets, and will increase flexibility and reduce burdens for states seeking to use section 1332 waivers as a means of innovation for providing coverage, lowering premiums, and improving their health care markets.

Permitting the Secretaries to modify the public notice procedures, in part, when a delay would undermine or compromise the purpose of the proposed section 1332 waiver request and be contrary to the interests of consumers will help states seeking section 1332 waivers to address such circumstances more quickly to ensure consumers have access to affordable health care coverage throughout the emergent situation. As such, the Departments explained they are of the view that, if certain safeguards are met, it is in the best interest of the public to provide states applying for section 1332 waivers with the option to request to modify otherwise applicable public notice procedures during an emergent situation. Based on the experience with the current COVID-19 PHE, the Departments noted they are of the view that it is appropriate and reasonable to propose to make similar flexibilities available in future emergent situations.

The Departments proposed to modify 31 CFR 33.118(a) and 45 CFR 155.1318(a) to provide that the Secretaries may modify, in part, the state public notice requirements specified in 31 CFR 33.112(a)(1), (b), (c), and (d) and 45 CFR 155.1312(a)(1), (b), (c), and (d) and the Federal public notice requirements specified at 31 CFR 33.116(b) and 45 CFR 155.1316(b) to expedite a decision on a proposed section 1332 waiver request during an emergent situation, when a delay would undermine or compromise the purpose of the proposed waiver request and would be contrary to the interests of consumers. As proposed, the amendments to 31 CFR 33.118(a) and 45 CFR 155.1318(a) further specified that these flexibilities would be limited to emergent situations, including natural disasters; PHEs; or other emergent situations that threaten consumers' access to health insurance coverage,

consumers' access to health care, or human life.

As noted earlier in this section of the preamble, under the proposal, the existing flexibility made available in the November 2020 IFC¹⁸⁷ for the COVID-19 PHE would continue to apply. The Departments also clarified that, similar to the November 2020 IFC, they were *not* proposing to allow states to waive 31 CFR 33.112(a)(2) and 45 CFR 155.1312(a)(2), which require states to conduct a separate process for meaningful consultation with federally-recognized tribes. The Departments noted that tribal consultation is subject to separate requirements in accordance with E.O. 13175,¹⁸⁸ which mandates the establishment of regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications.

In addition, the Departments clarified that a state cannot use this flexibility to request to eliminate public notice and participation procedures. Instead, this is a targeted proposal intended to extend the existing COVID-19 PHE flexibilities to future emergent situations to remove potential barriers and allow both the Federal Government and states flexibility to respond to emergent situations as they unfold. It is limited to permitting states to request to modify, in part, certain otherwise applicable public notice and participation requirements, not to eliminate the requirements all together.

Examples of the public notice and participation procedures that currently apply that, under this proposal, a state may seek to have waived or modified during a future emergent situation include the requirement that the state notifies the public and holds hearings prior to submitting an application, that the state hold more than one public hearing in more than one location, and that the Departments provide for public notice and comment after an application is determined to be complete. States may also seek to modify the state and/or Federal comment periods to be less than 30 days and to host public hearings virtually rather than in person.

In addition, the Departments explained they are of the view that these flexibilities are necessary to allow states flexibility to respond to rapid changes in the event of a future emergent situation and noted that these proposals align with existing flexibilities available

¹⁸⁷ See 85 FR 71142, <https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency>.

¹⁸⁸ See 85 FR 71142, 71178.

for public health programs that do not apply to section 1332 waivers. For example, when the President declares a disaster or emergency under the Stafford Act or the National Emergencies Act and the Secretary of HHS declares a PHE under section 319 of the PHS Act, section 1135 of the Act allows the Secretary of HHS to temporarily waive or modify certain Medicare, Medicaid, and CHIP requirements to ensure: (1) Sufficient health care items and services are available to meet the needs of individuals enrolled in these programs in the emergency area(s) and time periods; and (2) providers who give such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud and abuse). However, section 1135 of the Act does not apply to or otherwise provide the Departments with authority to waive or modify requirements regarding section 1332 waivers when similar events cause similar impacts in the private health insurance markets. As proposed, the modifications to the Departments' section 1332 waiver regulations outlined in the proposed rule were designed to generally align with the section 1135 flexibilities, but would be available in broader circumstances than emergencies or disasters declared under the Stafford Act or the National Emergencies Act and PHEs declared under section 319 of the PHS Act. The Departments proposed to apply this flexibility to include other emergencies at the state or local level to allow states to better address all of the various emergent situations that may impact their state health insurance markets and residents access to coverage and care.

Consistent with the existing framework for state modification requests related to the COVID-19 PHE, for a state request to modify the state or Federal public notice requirements to expedite a decision on a proposed section 1332 waiver request during an emergent situation to be approved, the state must meet the requirements outlined in 31 CFR 33.118(b) and 45 CFR 155.1318(b). As proposed, the Secretaries could approve a state's request to modify the Federal and/or state public notice procedures, in part, in future emergent situations if the state meets all of the following requirements:

- The state requests a modification in the form and manner specified by the Secretaries.
- The state acted in good faith, and in a diligent, timely, and prudent manner in the preparation of the request for the modification for the section 1332 waiver, and the waiver application request, as applicable.

- The state details in its request for a modification, as applicable, the justification for the requested modification from the state public notice procedures, and the alternative public notice procedures it proposes to implement at the state level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the state's request for a modification.

- The state details in its request for a modification, as applicable, the justification for the request and the alternative public notice procedures it requests to be implemented at the Federal level.

The Departments also proposed that the state, as applicable, must implement the alternative public notice procedures at the state level if the state's modification request is approved and, if required, amend the section 1332 waiver application to specify that it is the state's intent to comply with those alternative public notice procedures in the state's modification request. These are the same requirements that apply under the existing framework for state modification requests related to the COVID-19 PHE and are currently captured in 31 CFR 33.118(b)(1) through (4) and (f) and 45 CFR 155.1318(b)(1) through (4) and (f).¹⁸⁹

Any state submitting a proposed section 1332 waiver application during a future emergent situation could submit a separate request to the Secretaries to modify, in part, certain otherwise applicable state and/or Federal public notice and public participation requirements or could include such a request in its section 1332 waiver application request.

Consistent with the framework for COVID-19 PHE state modification requests, the Secretaries' review and consideration of a modification request for future emergent situations would vary based on the state's circumstances, its modification request, and the complexity and breadth of the state's proposed section 1332 waiver request. For example, during the COVID-19 PHE, many states prohibited in-person public gatherings or established stay-at-home orders due to the public health

threat.¹⁹⁰ States seeking new section 1332 waiver(s) that had such prohibitions in effect at the time they would have otherwise had to conduct public notice were unable to hold two in-person public hearings prior to submission of their section 1332 waiver applications. In similar future emergent situations, this approach would allow the Secretaries to grant the state's request to hold the two public hearings virtually, rather than in person, or to hold one public hearing at the state level, rather than two public hearings at the state level, if the state's request meets other applicable requirements. As another example, the Secretaries may agree with a state's determination that, due to emergent circumstances that have arisen related to a natural disaster, there is insufficient time for the state to provide public notice and hold any public hearings at the state level prior to submitting its section 1332 waiver application as would otherwise be required by 31 CFR 33.112(a) and 45 CFR 155.1312(a), and grant the state's request to provide public notice and hold public hearings at the state level after the state's submission of its application if the state's request meets other applicable requirements.

In situations where the Departments approve a state's modification request to provide public notice and host the state-level hearings on a different timeframe or setting, such as after the submission of a state's waiver application request, the state would be required to amend the application request as necessary to reflect public comments or other relevant feedback received during the alternative state-level public notice procedures. The Departments would evaluate a state's request for a modification of the public participation requirements and issue their modification determination within approximately 15 calendar days after the request is received. In assessing whether a state acted in good faith, and in a diligent, timely, and prudent manner in the preparation of the modification request for the waiver, and for the section 1332 waiver application, the Departments would evaluate whether the relevant circumstances are sufficiently emergent. The Departments proposed in new proposed 31 CFR 33.118(g) and 45 CFR 155.1318(g) that the Departments will consider circumstances to be emergent when they could not have been reasonably

¹⁸⁹ To effectuate the extension of these flexibilities to future emergent situations, the Departments proposed to amend 31 CFR 33.118(b)(3) and 45 CFR 155.1318(b)(3) to replace the current reference to "public health emergency" with "the emergent situation." This criterion otherwise remains the same.

¹⁹⁰ <https://khn.org/morning-breakout/states-declare-emergencies-ban-large-gatherings-as-coronavirus-sweeps-the-nation/>; <https://www.axios.com/states-shelter-in-place-coronavirus-66e9987a-a674-42bc-8d3f-070a1c0ee1a9.html>.

foreseen. In addition, the Departments proposed to assess “reasonable foreseeability” based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and would not make this assessment based solely on the number of days a state may have been aware of such issues. Other relevant factors that the Departments would consider include the specific circumstances involved, the nature and extent of the future emergent situation, and whether the state could have predicted the situation. To assist the Departments with making this assessment, the Departments also proposed to capture a new requirement at 31 CFR 33.118(b)(5) and 45 CFR 155.1318(b)(5) to require a state submitting a modification request must also explain in its request how the circumstances underlying its request result from a natural disaster; PHE; or other emergent situation that threatens consumers’ access to health insurance coverage, consumers’ access to health care, or human life that could not be reasonably have been foreseen and how a delay would undermine or compromise the purpose of the waiver and be contrary to the interests of consumers.

The Departments reminded states that any public participation processes must continue to comply with applicable Federal civil rights laws,¹⁹¹ including taking reasonable steps to provide meaningful access for individuals with LEP and taking appropriate steps to ensure effective communication with individuals with disabilities, including accessibility of information and communication technology. It is also important for states to remember that virtual meetings may present additional accessibility challenges for people with communication and mobility disabilities, as well as those who lack broadband access. The Departments noted that they expect states to take these considerations into account when seeking flexibility to modify the public participation requirements, as the overall statutory and regulatory obligation to ensure a meaningful level of public input during the public notice

and comment period would continue to apply. By way of example, ensuring effective communication during a future emergent situation when the otherwise applicable public notice and participation requirements are modified may include providing American Sign Language interpretation and real-time captioning as part of a virtual hearing, and ensuring that the platform used to host the hearing is interoperable with assistive technology for those with mobility difficulties. The Departments especially encouraged states to strive to obtain meaningful input from potentially affected populations, including low-income residents, residents with high expected health care costs, persons less likely to have access to care, and members of federally-recognized tribes, if applicable, as part of any alternative public participation process.

Consistent with the framework for COVID–19 PHE state modification requests, the Secretary of HHS would publish on the CMS website any modification determinations within 15 calendar days of the Secretaries making such a determination, as well as the approved revised timeline for public comment at the state and Federal level, as applicable.¹⁹² In addition, the state would be required to publish on its website any modification requests and determinations within 15 calendar days of receipt of the determination, as well as the approved revised timeline for public comment at the state and Federal level, as applicable.¹⁹³

The Departments sought comment on these proposals. The Departments summarize and respond to comments on the proposals related to Public Notice Procedures and Approval requirements captured in 31 CFR 33.118 and 45 CFR 155.1318 below alongside comments on the accompanying proposals to the Monitoring and Compliance in 31 CFR 33.120 and 45 CFR 155.1320. As detailed further later in this section of the preamble, the Departments are finalizing the amendments to 31 CFR 33.118(a), (b)(3), (b)(5) and (g) and 45 CFR 155.1318(a), (b)(3), (b)(5) and (g) with one modification. In response to comments and to align the regulations with the intended policy, we are replacing the reference to “health insurance coverage” with “comprehensive coverage” in the description of emergent situations in 31

CFR 33.118(a) and (b)(5) and 45 CFR 155.1318(a) and (b)(5).¹⁹⁴

b. Monitoring and Compliance (31 CFR 33.120 and 45 CFR 155.1320)

As section 1332 waivers are likely to have a significant impact on individuals, states, and the Federal Government, the 2012 Final Rule established processes and methodologies to ensure that the Secretaries receive adequate and appropriate information regarding section 1332 waivers (consistent with section 1332(a)(4)(B)(iv) of the ACA). As part of the Departments’ monitoring and oversight of approved section 1332 waivers, the Secretaries monitor the state’s compliance with the specific terms and conditions of the waiver, including, but not limited to, compliance with the guardrails, reporting requirements, and the post award forum requirements.¹⁹⁵ Under 31 CFR 33.120(c) and 45 CFR 155.1320(c), to ensure continued public input within at least 6 months after the implementation date, and annually thereafter, states are required to hold a public forum at which members of the public have an opportunity to provide comments on the progress of the program authorized by the section 1332 waiver and to provide a summary of this forum to the Secretary of HHS for the Departments’ review as part of the quarterly and annual reports required under 31 CFR 33.124 and 45 CFR 155.1324. Under 31 CFR 33.120(c)(1) and 45 CFR 155.1320(c)(1), states are required to publish the date, time, and location of the public forum in a prominent location on the state’s public website at least 30 days prior to the date of the planned public forum. In the November 2020 IFC, the Departments added 31 CFR 33.120(c)(2) and 45 CFR 155.1320(c)(2) to provide that the Secretaries may waive, in part, post award public notice requirements during the COVID–19 PHE when certain criteria were met.

¹⁹⁴ As finalized, the new regulatory text provides these flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers’ access to comprehensive coverage, consumers’ access to health care, or human life. Similarly, state requests to modify otherwise applicable public notice and participation requirements must explain how the emergent circumstances underlying the request result from a natural disaster; public health emergency; or other emergent situation that threatens consumers’ access to comprehensive coverage, consumers’ access to health care, or human life and could not reasonably have been foreseen.

¹⁹⁵ See section 1332(a)(4)(iv) and (v). Also see 31 CFR 33.120 and 45 CFR 155.1320.

¹⁹¹ See Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d, 45 CFR part 80), Section 1557 of the ACA (42 U.S.C. 18116), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794, 45 CFR part 84), and Title II of the Americans with Disabilities Act (42 U.S.C. 12131 *et seq.*, 28 CFR part 35). The HHS Office for Civil Rights enforces applicable Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, sex, age, or disability, as well as laws protecting the exercise of conscience and religious freedom, including the Religious Freedom Restoration Act (42 U.S.C. 2000bb through 2000bb–4).

¹⁹² See 31 CFR 33.118(d) and 45 CFR 155.1318(d).

¹⁹³ See 31 CFR 33.118(e) and 45 CFR 155.1318(e).

The Departments proposed to modify 31 CFR 33.120(c)(2) and 45 CFR 155.1320(c)(2), to extend the flexibilities currently provided during the COVID-19 PHE to permit the Secretaries to modify in part, certain post award public notice requirements in 31 CFR 33.120(c) and 45 CFR 155.1320(c) for approved waivers during a future emergent situation when the application of the post award public notice procedures would be contrary to the interests of consumers. Extending these flexibilities beyond the COVID-19 PHE to future emergent situations is important to help states as they may face similar uncertainty as to whether they are able to comply with the otherwise applicable post award requirements in such situations. For example, the state post award procedures generally require an in-person gathering. Based on the experience with the current COVID-19 PHE, the Departments explained they are of the view that it is appropriate and reasonable to propose to make similar flexibilities available in future emergent situations as those circumstances may also limit the ability for the state to host in-person gatherings. The Departments did not propose any changes with respect to the flexibility made available in the November 2020 IFC in response to the COVID-19 PHE and clarified that states with approved section 1332 waivers continue to have flexibility to submit requests to the Departments to modify certain post award public notice requirements during the COVID-19 PHE.¹⁹⁶

Consistent with the framework for state modification requests related to the COVID-19 PHE, as proposed, the Secretaries could similarly approve a state request to modify the post award public notice procedures, in part, when the application of the post award public notice requirements would be contrary to the interest of consumers during the future emergent situation. The Departments proposed to amend the title in 31 CFR 33.120(c)(2) and 45 CFR 155.1320(c)(2) and to amend the text at 31 CFR 33.120(c)(2)(i) and 45 CFR 155.1320(c)(2)(i) to replace the references to “the public health emergency” with “an emergent situation.” The Departments also proposed amendments to the last sentence of 31 CFR 33.120(c)(2)(i) and 45 CFR 155.1320(c)(2)(i) to replace the language that limits these flexibilities to the COVID-19 PHE to reflect the broader proposed applicability to emergent situations, including natural disasters; PHEs; or other emergent

situations that threaten consumers’ access to health insurance coverage, consumers’ access to health care, or human life. In addition, the Departments proposed that the Secretaries could approve a state’s post award modification request if the state meets all of the following requirements:

- The state requests a modification in the form and manner specified by the Secretaries.
- The state acts in good faith, and in a diligent, timely, and prudent manner to comply with the monitoring and compliance requirements under the regulations and specific terms and conditions of the section 1332 waiver and to submit and prepare the request for a modification.
- The state details in its request for a modification the reason(s) for the alternative post award public notice procedures it proposes to implement at the state level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergent circumstances underlying the state’s request for a modification.

These are the same requirements that apply under the existing framework for state post award modification requests related to the COVID-19 PHE currently captured in 31 CFR 33.120(c)(2)(ii)(A) through (C) and 45 CFR 155.1320(c)(2)(ii)(A) through (C).

As proposed, a state may request to modify the otherwise applicable public participation requirements to host the public forum for an approved section 1332 waiver that would take place or become due during an emergent situation virtually rather than as an in-person gathering. When reviewing state modification requests, the Departments would remain focused on ensuring the public is informed about the implementation of programs authorized by section 1332 waivers and has a meaningful opportunity to comment on its implementation.

Consistent with the framework for COVID-19 state modification requests, the Secretaries would evaluate a state’s request for a modification of certain post award public participation requirements during a future emergent situation and issue their modification determination within approximately 15 calendar days after the request is received.¹⁹⁷ The state would be required to publish on its website any modification requests and determinations by the Departments within 15 calendar days of receipt of the determination, as well as information on

the approved revised timeline for the state’s post award public notice procedures, as applicable.¹⁹⁸ Since the state is already required to post materials as part of post award annual reporting requirements, such as the notice for the public forum and annual report, states would be responsible for ensuring that the public is aware of the determination to modify the public notice procedures and would be required to include this information along with the other information required under 31 CFR 33.120(c)(1) and 45 CFR 155.1320(c)(1) for the alternative procedures in a prominent location on the state’s public website.

The Departments explained they are of the view that post award public forums are critical to ensure that the public has a regular opportunity to learn about and comment on the progress of section 1332 waivers. Based on the experience during COVID-19 PHE, the Departments explained they are of the view that it is appropriate and reasonable to propose to provide similar flexibilities and permit states to request to modify certain post award public participation requirements in future emergent situations. States that receive approval to modify, in part, these post award public notice procedures would still need to meet all other applicable requirements specified in 31 CFR 33.120(c) and 45 CFR 155.1320(c). For example, if the state receives a modification approval that permits it to hold the post award public forum virtually instead of in person, the state must still publish the notice of its post award public forum on the state’s public website and use other effective means to communicate the required information to the public. The public notice must include the website, date, and time of the public forum that will be convened by the state, information related to the timeframe for comments, and how comments from the public on the section 1332 waiver must be submitted. The Departments reminded states that they still must also comply with applicable Federal civil rights requirements, including laws pertaining to accessibility, if the Secretaries approve a modification from post award public notice procedures. For example, a state that receives approval to host the required public hearing(s) virtually would need to ensure the hearings are accessible to individuals with disabilities and individuals with LEP so members of the public can participate and submit comments. The state should

¹⁹⁶ See 85 FR 71142.

¹⁹⁷ See 31 CFR 33.120(c)(2)(ii)(D) and 45 CFR 155.1320(c)(2)(ii)(D).

¹⁹⁸ See 31 CFR 33.120(c)(2)(ii)(E) and 45 CFR 155.1320(c)(2)(ii)(E).

also track how many people are attending these forums, if possible.

In assessing whether a state acted in good faith, and in a diligent, timely, and prudent manner when reviewing a state's post award modification request, the Departments would evaluate whether the relevant circumstances are sufficiently emergent. The Departments proposed in 31 CFR 33.120(c)(2)(iii) and 45 CFR 155.1320(c)(2)(iii) that the Departments will consider circumstances to be emergent when they could not have been reasonably foreseen. In addition, the Departments proposed to assess "reasonable foreseeability" based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and would not make this assessment based solely on the number of days a state may have been aware of such issues. Other relevant factors that the Departments would consider include the specific circumstances involved, the nature and extent of the emergent situation, and whether the state could have predicted the situation. To assist the Departments with making this assessment the Departments also proposed to capture a new requirement at 31 CFR 33.120(c)(2)(ii)(F) and 45 CFR 155.1320(c)(2)(ii)(F) to require a state submitting a post award modification request to also explain in its request how the circumstances underlying its request result from a natural disaster; PHE; or other emergent situation that threatens consumers' access to health insurance coverage, consumers' access to health care, or human life and could not be reasonably have been foreseen and how application of the post award public notice requirements would be contrary to the interests of consumers.

The Departments sought comment on this proposal.

The following is a summary of the comments received and the Departments' responses to our proposals to amend 31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR 155.1320 to permit the Secretaries to modify, in part, the normal public notice requirements for section 1332 waivers in future emergent situations.

Comment: The Departments received comments in support of the proposals to modify 31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR 155.1320. In addition, one commenter recommended that the Departments codify as part of the regulatory text the "reasonably foreseeable" definition for emergent situations. Another commenter recommended that the section 1332 waiver process should more closely mirror the section 1115 demonstration program emergency

process. This commenter had concerns about the vagueness of both the definition of "emergency" and the definition of "health insurance coverage"—specifically, the latter not being defined as comprehensive—and that the proposed flexibilities could be "subject to misuse" as a result. Another commenter requested that the Departments provide further guidance or examples of situations the Departments will consider unforeseeable and urgent threats to consumers' access to health insurance coverage, consumers' access to health care, or human life so states can better understand when these flexibilities may be available. One commenter recommended that the Departments extend the flexibilities demonstrated during the COVID-19 PHE, not just for other emergent situations, but regardless of whether the circumstances are emergent or not. This commenter explained that extending these policies beyond emergencies would foster the goals of the statute by providing the public an opportunity for meaningful access and participation in the public notice process. This commenter noted that extending this policy more generally would help individuals with LEP and individuals with disabilities since online tools make participation possible and may exceed what is available at a time- and space-restricted in-person forum.

Response: The Departments appreciate commenters' support for the proposals to extend the COVID-19 flexibilities to modify, in part, the otherwise applicable public participation requirements and are finalizing these policies and clarifications as proposed. The Departments are not finalizing additional changes to the rule text at this time.

The Departments considered but did not propose extending these flexibilities regardless of whether the circumstances are emergent or not. The Departments proposed and are finalizing the extension of these flexibilities to address when current requirements are barriers for states during emergent situations. This policy is targeted at providing a reprieve from certain requirements to allow the Federal Government and states to respond to emergent situations as they unfold. States will be required to meet the otherwise applicable public participation requirements in all other circumstances. Furthermore, there is also no requirement that precludes states from utilizing online tools for their public participation requirements forums in addition to in-person forums

to better meet the needs of populations such as those with disabilities or LEP.

The Departments decline to adopt a specific definition for "reasonable foreseeability" or further define the exact number of days that the state must not have been aware of such issues. The Departments are of the view that such a determination would depend heavily on the specific facts and circumstances involved, including the nature and extent of the emergent situation. The Departments are finalizing the proposal to assess "reasonable foreseeability" based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and would not make this assessment based solely on the number of days a state may have been aware of such issues. Other relevant factors that the Departments will consider include the specific circumstances involved, the nature and extent of the future emergent situation, and whether the state could have predicted the situation. The justification and other information submitted by the state as part of its modification request will also be considered. The Departments are of the view that this general framework allows the Departments to strike a balance in accounting for states experiencing different kind of emergencies, while also providing states with information on the factors the Departments will use when making this determination. For example, a state that experiences a hurricane, which often happens quickly and may impact the state's ability to hold an in-person hearing, would likely have little lead time to request and plan for a change. Furthermore, a state could experience a new emergent situation that could lead to limited or no Exchange plan options in a geographic area—perhaps from a very recent and sudden economic downturn, issuer insolvency, or other reasons—that could threaten consumers' access to health insurance coverage or care. In this scenario, the state would likely have more lead time compared to a natural disaster, such as a hurricane or flooding, but the issue could become emergent at various points during the rate submission or QHP certification process. For example, the Departments would not consider an ongoing recession, by itself, to be an emergent situation. The Departments further note that existing threats to consumers' access to health coverage or care—such as in geographic areas in which issuer participation has been historically low—would not be considered emergent situations for purposes of applying the flexibilities finalized in this rule. After

receipt of a state's modification request, the Departments will also examine what is in the best interest of the public and whether allowing the state to modify the full public participation requirements would do undue harm to the public. This evaluation will also take into account other relevant factors and information, including information provided by the state regarding how the emergent situation could not reasonably have been foreseen and how a delay would undermine or compromise the purpose of the waiver and be contrary to the interest of consumers.

The Departments are not providing additional examples of situations they may consider "reasonably unforeseen" at this time but will consider doing so in the future. States that may be interested in using these flexibilities during an emergent situation should reach out to the Departments as soon as practicable to help determine if the situation would meet the requirements outlined in this rule.

While section 1115 demonstration projects do not have emergency processes for situations that threaten access to health insurance coverage, it is the Departments' view that these flexibilities for an emergent situation are important for section 1332 waivers for the private health insurance market. In addition, the Departments clarify that for the purposes of this flexibility to address emergent situations that threaten consumers' access to health insurance coverage, the reference to "health insurance coverage" was intended to capture comprehensive coverage as defined under 31 CFR 33.108(f)(3)(iv)(A) and 45 CFR 155.1308(f)(3)(iv)(A) such that situations that threaten consumers' access to comprehensive coverage that meets the requirements for EHBs as defined in section 1302(b) of the ACA and offered through Exchanges established by title I of the ACA, or, as appropriate, Medicaid or CHIP, may be considered emergent under this rule. Similarly, the reference was intended to align with the policies and interpretations finalized in this rule regarding the coverage guardrail and to capture the different forms of MEC as defined in 26 U.S.C. 5000A(f). In response to comments and to align the regulations with the intended policies and interpretations, we are updating 31 CFR 33.118(a) and (b)(5), 31 CFR 33.120(c)(2)(i) and (c)(2)(ii)(F), 45 CFR 155.1318(a) and (b)(5), and 45 CFR 155.1320(c)(2)(i) and (c)(2)(ii)(F) to replace the references to "health insurance coverage" with

"comprehensive coverage" in the description of emergent situations.¹⁹⁹

Comment: The Departments received several comments encouraging the Departments to withdraw the proposals to modify 31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR 155.1320 related to extending the COVID-19 PHE flexibilities to future emergent situations. These commenters voiced concerns that the proposals would allow states to avoid providing the public a meaningful opportunity to provide input on waiver plans, as required by the statute. Some of these commenters were concerned that the revised public notice requirements risk unintended negative consequences for consumers. They noted that various stakeholders, including state advocates, rely on these public comment periods to provide feedback on how waiver proposals will impact consumers and other key stakeholders. The commenters expressed the view that the proposed flexibilities would allow states to cut short the notice and comment periods, thereby not allowing for a meaningful level of public input. Furthermore, these commenters were of the view that the proposed flexibilities would delay the public notice procedures until after the Departments make a decision on a waiver application request. These commenters also noted that section 1332 waivers are designed to implement health system innovations, not to respond to disasters and other emergencies. They also cited that Congress has provided other authorities to respond to natural disasters and other emergencies.

Response: The Departments appreciate and understand the concerns raised by these commenters; however, as explained earlier and in the proposed rule, the flexibilities provided under this rule do not allow states to avoid providing notice and an opportunity to comment on proposed waiver applications. Consistent with section 1332(a)(4)(B)(i) of the ACA and regulations at 31 CFR 33.112 and 45 CFR 155.1312, states will continue to be required to provide a public notice and

comment period for section 1332 waiver applications sufficient to ensure a meaningful level of public input prior to approval or denial of an application. States with approved section 1332 waivers will similarly be required to provide a meaningful opportunity to comment during post award public forums. Stakeholders and the general public will continue to be able to provide feedback on the impact of waiver proposals. As explained in this preamble, the Departments value the importance of the public input process, but are finalizing the flexibility to permit the adjustment of certain requirements, where appropriate, in emergent situations.

In finalizing these policies, the Departments intend to permit states to request to modify the public notice procedures for proposed waiver applications, *in part*, when a delay would undermine or compromise the purpose of the proposed section 1332 waiver request and be contrary to the interests of consumers. States will also be permitted to request to modify the post award requirements, *in part*, when the application of those requirements would be contrary to the interests of consumers. The Departments again reiterate that a state cannot use this flexibility to eliminate public notice and participation procedures.²⁰⁰ In addition, states cannot waive the requirement to conduct a separate process for meaningful consultation with federally-recognized tribes. States must also continue to comply with applicable civil rights laws, including requirements related to providing meaningful access for individuals with LEP and effective communication with individuals with disabilities. This rule is a targeted policy to extend the existing COVID-19 PHE flexibilities to future emergent situations to remove potential barriers and allow both the Federal Government and states flexibility to respond to emergent situations as they unfold. States can seek to use these flexibilities to modify the requirement to hold more than one public hearing in more than one location, to hold public hearings before submission of the waiver application to the Departments, or to hold the hearings virtually rather than in-person. The Departments expect states will take into account relevant considerations when seeking flexibility

¹⁹⁹ As finalized, the new regulatory text provides these flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care or human life. Similarly, state requests to modify otherwise applicable public notice and participation requirements must explain how the emergent circumstances underlying the request result from a natural disaster; public health emergency; or other emergent situation that threatens consumers' access to comprehensive coverage, consumers' access to health care or human life and could not reasonably have been foreseen.

²⁰⁰ The state's request must detail the justification for and the alternative public notice procedures it seeks to implement that are designed to provide the greatest opportunity and level of public input from impacted stakeholders practicable given the emergent circumstances underlying the state's request. See 31 CFR 33.118(b)(3) and 45 CFR 155.1318(b)(3).

to modify the public participation requirements and that states will address these considerations in modification requests. For example, when evaluating a state's request to conduct a virtual hearing during a future emergent situation, the Departments may evaluate, among other relevant factors, what steps the state outlines in its modification request in response to the additional accessibility challenges that such hearings entail.

The Departments also reiterate that in situations where the Departments approve a state's modification request to provide public notice and host the state-level hearings on a different timeframe or in a different setting, such as after the submission of a state's waiver application request, the state would be required to amend the application request as necessary to reflect public comments or other relevant feedback received during the alternative state-level public notice procedures. The state would also be required to publish on its website any modification requests and determinations, as well as publish information on the approved revised timeline to inform the public about the alternative timeline or procedures. The Departments further clarify and affirm that they do not intend to approve or deny a waiver application request until after completion of the modified public notice procedures at the state or Federal level, as applicable, and consideration of timely submitted public comments.

Finally, these flexibilities have been important during the COVID-19 PHE and have furthered efforts to prevent the spread of COVID-19 by limiting the need for in-person gatherings related to section 1332 waivers. During the COVID-19 PHE, 14 states with approved section 1332 waivers have utilized the flexibilities outlined in the November 2020 IFC to meet the section 1332 public notice requirements while ensuring the safety of state residents by holding virtual forums.²⁰¹ Furthermore, states have found virtual forums more beneficial in terms of reaching more rural or hard-to-reach populations, when compared to in-person gatherings. Finally, the Departments acknowledge there are similar flexibilities available under section 1115 demonstrations for Medicaid and CHIP, as well as under section 1135 waivers for Medicare, Medicaid, and CHIP. These amendments to 31 CFR 33.118, 31 CFR 33.120, 45 CFR 155.1318, and 45 CFR

155.1320 provide for similar treatment of section 1332 waivers.

The Departments appreciate commenters' concern that section 1332 waivers are not intended to respond to disasters and other emergencies, but are of the view that these situations could lead to an acute need for health insurance coverage and that section 1332 waivers can be used to help address these challenges and promote market stability.

After consideration of these comments, the Departments are finalizing the modifications to 31 CFR 33.118(a), (b)(3), (b)(5) and (g); 31 CFR 33.120(c)(2); 45 CFR 155.1318(a), (b)(3), (b)(5) and (g); and 45 CFR 155.1320(c)(2) and the adoption of the accompanying policies, interpretations, and clarifications as explained in this section of this preamble.

7. Monitoring and Compliance (31 CFR 33.120 and 45 CFR 155.1320)

The Departments proposed to modify 31 CFR 33.120(a)(1) and (2) and 45 CFR 155.1320(a)(1) and (2) to remove the reference, as codified under part 1 of the 2022 Payment Notice final rule, to interpretive guidance published by the Departments. The proposal aligns the Departments' efforts to provide supplementary information about the requirements that must be met for the continued oversight and monitoring of an approved section 1332 waiver. Because the Departments are of the view that the 2018 Guidance and the incorporation of its guardrail interpretations into regulations could result in the Departments approving section 1332 waivers that would result in fewer residents in those states enrolling in comprehensive and affordable coverage, that those interpretations do not represent the best fulfillment of congressional intent behind the statutory guardrails, that they are inconsistent with the policy intentions of E.O. 14009 and E.O. 13985, and that it is appropriate to address concerns raised by commenters on the 2018 Guidance, the Departments proposed to remove the reference to the 2018 Guidance. As proposed, the Departments would rely upon the statute and regulations, as well as the Departments' interpretive policy statements as outlined in the applicable notice and comment rulemaking, in monitoring approved section 1332 waivers.

The following is a summary of the comments received and the Departments' responses to our proposals to amend 31 CFR 33.120(a)(1) and (2) and 45 CFR 155.1320(a)(1) and (2).

Comment: The Departments received some comments expressing general support for removing the reference to guidance from the rule text. In addition, one commenter specifically supported the proposal to monitor approved section 1332 waivers according to the statute, regulations, and interpretative policy described in notice and comment rulemaking, and removing the reference to the 2018 guidance.

Response: The Departments appreciate commenters' support. After consideration of these comments, the Departments are finalizing these proposed modifications to 31 CFR 33.120(a)(1) and (2) and 45 CFR 155.1320(a)(1) and (2).

8. Pass-Through Funding (31 CFR 33.122 and 45 CFR 155.1322)

Section 1332(a)(3) of the ACA directs the Secretaries to pay pass-through funding to the state for the purpose of implementing the state section 1332 waiver plan and outlines accompanying requirements for making the pass-through funding determination. The Departments proposed new regulation text at 31 CFR 33.122 and 45 CFR 155.1322 to codify in regulation details regarding the Departments' determination of pass-through funding for approved section 1332 waivers. More specifically, the Departments proposed to codify in regulation that, with respect to a state's approved section 1332 waiver, the amount of Federal pass-through funding would equal the amount, determined annually by the Secretaries, of the PTC under section 36B of the Code, the small business tax credit (SBTC) under section 45R of the Code, or CSRs under ACA part I of subtitle E (collectively referred to as Federal financial assistance), that individuals and small employers in the state would otherwise be eligible for had the state not received approval for its section 1332 waiver. This calculation would include any amount not paid due to an individual not qualifying for Federal financial assistance or qualifying for a reduced level of such financial assistance. The pass-through amount would not be increased to account for any savings other than the reduction in Federal financial assistance. The pass-through amount would be reduced by any net increase in Federal spending or net decrease in Federal revenue if necessary to ensure deficit neutrality. The pass-through estimates take into account experience in the relevant state and the experience of other states with respect to participation in an Exchange and credits and reductions provided under such provisions to residents of the other

²⁰¹ States with approved waivers that have held public notice requirements virtually during the COVID-19 PHE include Alaska, Colorado, Delaware, Hawaii, Maine, Maryland, Minnesota, Montana, New Hampshire, North Dakota, Oregon, Pennsylvania, Rhode Island, and Wisconsin.

states. This amount would be calculated annually by the Departments and could be updated by the Departments as necessary to reflect applicable changes in Federal or state law. The proposed regulations further state, consistent with the statute,²⁰² that any pass-through funding can only be used for purposes of implementing the state's approved section 1332 waiver plan.

Consistent with the Departments' existing regulations at 31 CFR 33.108(f)(4) and 45 CFR 155.1308(f)(4), section 1332 waiver applications are required to provide analysis and supporting data to inform the Department's estimate of the pass-through funding amount and the waivers' predicted impact on the deficit neutrality guardrail. For states that do not utilize an FFE, this includes information about enrollment, premiums, and Federal financial assistance in the state's Exchange by age, income, and type of policy, and other information as may be required by the Secretaries. Consistent with the Departments' existing regulations at 31 CFR 33.124 and 45 CFR 155.1324, states with approved section 1332 waivers must comply with state reporting requirements in accordance with the terms and conditions of the state's section 1332 waiver. If pass-through funding is being sought as part of the state's section 1332 waiver plan, states may also be required to submit data as outlined in the specific terms and conditions for the state's approved waiver in order for the Departments to calculate pass-through funding. The Departments did not propose any changes to these waiver requirements.

In addition, the proposals do not change the existing requirements codified in 31 CFR 33.108(f)(3)(iii) and 45 CFR 155.1308(f)(3)(iii) for the state's section 1332 waiver application to include a description of the provisions for which the state seeks a section 1332 waiver and how the waiver is necessary to facilitate the state's waiver plan. The Departments proposed that, if the state is seeking pass-through funding, the state waiver application should include an explanation of how, due to the structure of the section 1332 state plan and the statutory provisions waived, the state anticipates that individuals would no longer qualify for Federal financial assistance or would qualify for reduced Federal financial assistance, as a result of the section 1332 waiver.²⁰³ In

addition, the Departments proposed the state would also need to explain in its application how the state intends to use that funding for the purposes of implementing its section 1332 state plan.

The Departments sought comment on the proposals, including the proposed adoption of the new regulatory text on pass-through funding for approved section 1332 waivers. The Departments received some comments regarding pass-through funding in connection with the Departments' proposals related to the deficit neutrality guardrail and those comments are summarized and responded to in this preamble at section IV(3)(d) of this final rule.

Comment: The Departments received a comment expressing general support for codifying the proposed interpretation related to pass-through funding.

Response: The Departments appreciate this commenter's support. After consideration of the comments on pass-through funding, the Departments are finalizing the adoption of these proposed policies and the codification of these new regulations.

9. Periodic Evaluation Requirements (31 CFR 33.128 and 45 CFR 155.1328)

The Departments proposed to modify 31 CFR 33.128(a) and 45 CFR 155.1328(a) to remove the reference, as codified under part 1 of the 2022 Payment Notice final rule, to interpretive guidance published by the Departments. The proposal aligns the Departments' efforts to provide supplementary information about the requirements that must be met for the periodic evaluation requirements of an approved section 1332 waiver. Because the Departments are of the view that the 2018 Guidance and the incorporation of its guardrail interpretations into regulations could result in the Departments approving section 1332 waivers that would result in fewer residents in those states enrolling in comprehensive and affordable coverage, that those interpretations do not represent the best fulfillment of Congressional intent behind the statutory guardrails, that they are inconsistent with the policy intentions of E.O. 14009 and E.O. 13985, and that it is appropriate to address concerns raised by commenters on the 2018 Guidance, the Departments proposed to remove the reference to the 2018 Guidance. As proposed, the Departments would rely upon the statute and regulations, as well as the Departments' interpretive policy statements as outlined in the applicable notice and comment rulemaking, in

conducting periodic evaluations of approved section 1332 waivers.

The following is a summary of the comments received and the Departments' responses to the proposals to amend 31 CFR 33.128(a) and 45 CFR 155.1328(a).

Comment: The Departments received some comments expressing general support for removing the reference to guidance from the rule text.

Response: The Departments appreciate commenters' support. After consideration of these comments, the Departments are finalizing the proposed modifications to 31 CFR 33.128(a) and 45 CFR 155.1328(a).

10. Waiver Amendment (31 CFR 33.130 and 45 CFR 155.1330)

The Departments proposed new regulations at 31 CFR 33.130 and 45 CFR 155.1330 to delineate the process by which a state is permitted to submit an amendment to an approved section 1332 waiver. The proposed new regulations also capture a proposed definition of a section 1332 waiver amendment. While the statute does not specifically mention amendment requests, some states with approved section 1332 waivers have indicated interest in amending their current approved waiver plans. Further, in response to previously received comments on the 2012 Final Rule, the Departments acknowledged that information regarding section 1332 waiver amendments and renewals would be needed in the future,²⁰⁴ and the Departments have received several inquiries from states on these topics. In addition, there may be situations where states pursuing proposed section 1332 waiver plans are interested in amending an application that has been submitted to the Departments for review. The Departments proposed that the framework would only apply to amendments to approved section 1332 waiver plans and would not apply to changes to an initial section 1332 waiver application submitted to the Departments but unapproved.²⁰⁵ Under this proposal, a state would not be authorized to implement any aspect of the proposed amendment without prior approval by the Departments.

In the proposed rule, the Departments set forth a proposed procedural

²⁰⁴ See 77 FR 11700.

²⁰⁵ In circumstances where a state wants to amend its waiver application before the Departments have approved the waiver plan, the Departments intend to work with the state to ensure there is an adequate, meaningful opportunity for public notice and comment taking into account the particular circumstances of the situation and the state's waiver application (such as the changes to the proposed waiver, timing, etc.).

²⁰² See section 1332(a)(3) of the ACA.

²⁰³ While this rule generally finalizes the proposal to supersede and rescind the 2018 Guidance, the Departments are finalizing these standards which align with the approach outlined in the 2018 Guidance.

framework for submission and review of amendment requests for an approved section 1332 waiver. The Departments explained they are of the view that this additional information will help states with approved section 1332 waiver plans better plan for and prepare for potential amendments to their state waiver plans. The Departments also noted they intend to continue providing information and details regarding the section 1332 waiver amendment process in the specific terms and conditions for an approved waiver plan. The proposals were intended to align with the current amendment request process outlined in recent specific terms and conditions (STCs) for states with approved waivers.²⁰⁶

a. Definition of Waiver Amendment

For purposes of these requirements, the Departments proposed to define the term “section 1332 waiver amendment” as a change to a section 1332 waiver plan that is not otherwise allowable under the STCs of an approved waiver, a change that could impact any of the section 1332 statutory guardrails, or a change to the program design for an approved waiver. Such potential changes include, but are not limited to, changes to eligibility, coverage, benefits, premiums, out-of-pocket spending, and cost sharing. The Departments proposed to codify this definition in new proposed 31 CFR 33.130(a) and 45 CFR 155.1330(a).

b. Waiver Amendment Process

To request a waiver amendment, the Departments proposed that the state must submit a letter in electronic format to the Departments to notify them in writing of its intent to request an amendment to its approved section 1332 waiver plan(s). The state would be required to include a detailed description of all of the intended change(s), including the proposed implementation date(s), in its letter of intent. The Departments explained they would encourage the state to submit the letter of intent at least 15 months prior to the section 1332 waiver amendment’s proposed implementation date and to engage with the Departments early in its development of a potential waiver amendment. The state may want to submit this letter of intent more than 15 months prior to the section 1332 waiver amendment’s proposed implementation date, depending on the complexity of the amendment request and the timeline

for implementation, among other factors.

The Departments would review the state’s letter of intent request. The Departments proposed that, within approximately 30 days of the Departments’ receipt of the letter of intent, the Departments would respond to the state and confirm whether the change requested is a section 1332 waiver amendment, as well as identify the information the state needs to submit in its waiver amendment request. This written response would also include whether or not the proposed section 1332 waiver amendment(s) would be subject to any additional or different requirements. For example, depending on the complexity of the section 1332 amendment request, scope of changes from the approved waiver plan, operational/technical changes, or implementation considerations, the Departments may impose requirements similar to those specified in 31 CFR 33.108(f) and 45 CFR 155.1308(f) for initial section 1332 waiver applications. The preamble regarding section 1332 waiver amendment content that follows further describes the proposed content requirements for section 1332 waiver amendment requests.

Under the proposed section 1332 waiver amendment framework, the state should generally plan to submit its waiver amendment request no later than 9 months prior to when the proposed amendment would take effect in order to allow for sufficient time for review of the waiver amendment request. Similar to the regulations at 31 CFR 33.108(a) and 45 CFR 155.1308(a) for new section 1332 waiver applications, the Departments proposed that applications for waiver amendments of a section 1332 waiver must be submitted in electronic format to the Departments. Similar to the regulations at 31 CFR 33.108(b) and 45 CFR 155.1308(b) for new section 1332 waiver applications, the Departments proposed that the state would be required to submit the section 1332 waiver amendment request sufficiently in advance of the requested waiver implementation date, particularly when the waiver plan impacts premium rates, to allow for an appropriate review and implementation timeframe. Depending on the complexity of the section 1332 amendment request, the state may want to submit the amendment request earlier than 9 months prior to implementation. In developing the implementation timeframe for its section 1332 waiver amendment request, the Departments proposed that the state must maintain uninterrupted operations of the

Exchange in the state and provide adequate notice to affected stakeholders and issuers of health insurance plans that would be (or may be) affected by the amendment to take necessary action based on approval of the section 1332 waiver amendment request. As detailed later in this section of this preamble, these are operational details that the state would be required to address as part of its waiver amendment request. In addition, as reflected in the new proposed regulations at 31 CFR 33.130(a) and 45 CFR 155.1330(a), a state would not be authorized to implement any aspect of the proposed amendment without prior approval from the Secretaries.

The Departments proposed a similar process for section 1332 waiver amendment requests as is outlined for new section 1332 waiver applications in 31 CFR 33.108 and 45 CFR 155.1308. In line with these requirements, the Departments proposed to define the type of information and what information a state is required to provide to the public prior to the submission of a section 1332 waiver amendment request to the Departments. Similar to new section 1332 waiver applications, the Departments proposed to evaluate the state’s section 1332 waiver amendment request and may approve the request if the waiver, as amended, meets the statutory guardrails as defined in section 1332(b)(1)(A)-(D) of the ACA and other applicable requirements. In general, states are permitted to have a waiver plan that consists of different components or parts. As proposed, states would be permitted to propose an amendment, which could build on an approved section 1332 waiver plan. The Departments proposed that a state’s approved section 1332 waiver plan and the proposed waiver amendment request should be analyzed together, and the state would receive pass-through funding for implementation of the amended waiver plan (including the amendment, if approved) if the amended waiver plan yields Federal financial assistance savings, net of any reductions necessary to ensure deficit neutrality. For example, if a state has an approved reinsurance program for plan year 2021 through 2025, and is seeking approval for a waiver amendment request to begin in 2023, the analysis in the section 1332 waiver amendment request should demonstrate that the reinsurance program combined with any proposed amendments meets the guardrails. In comparing scenarios with and without the section 1332 waiver, the Departments proposed to consider

²⁰⁶ For example, see STC 9 in New Hampshire’s Approval Letter and STCs: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-NH-Approval-STCs.pdf>.

the without-waiver scenario to include neither the reinsurance program nor the section 1332 waiver amendment request and the with-waiver scenario to include the combined impact of the reinsurance program and the section 1332 waiver amendment request. In terms of pass-through funding, the Departments proposed that, if the section 1332 waiver amendment request described in the example is approved and determined to yield additional reductions in Federal financial assistance (in the form of PTC, CSR, or SBTC), the state would continue to receive pass-through funding annually for combined reductions in Federal financial assistance for the entire section 1332 waiver plan, rather than receiving a separate pass through funding amount for the reinsurance component of the waiver and a separate pass-through funding amount for the waiver amendment component. As noted in the earlier in preamble on pass-through funding, such amounts could be updated by the Departments, as necessary, to reflect applicable changes in state or Federal law.

Similar to the requirements in 31 CFR 33.108 and 45 CFR 155.1308, the Departments also proposed that the public must have a meaningful opportunity to provide input at the state and Federal level on waiver amendment requests. Section 1332(a)(4)(B) of the ACA requires the Secretaries to issue regulations that provide a process for public notice and comment at the state level, including public hearings, that is sufficient to ensure a meaningful level of public input. The Departments propose that a state pursuing a section 1332 waiver amendment must conduct the state public notice process that is specified for new applications at 31 CFR 33.112 and 45 CFR 155.1312. As such, to ensure a meaningful level of public input, the comment period would generally need to be no less than 30 days. The Departments also proposed that it would be permissible for a state to use its annual public forum required under 31 CFR 33.120(c) and 45 CFR 155.1320(c) for the dual purpose of soliciting public input on a proposed section 1332 waiver amendment request and on the progress of its approved waiver plan. This policy proposal is in line with the flexibility the Departments permitted in the 2012 Final Rule section 1332 regulations²⁰⁷ to allow for states to use Medicaid tribal consultation to also satisfy the requirements as set forth in 31 CFR 33.112(a)(2) and 45 CFR 155.1312(a)(2), that require a state with one or more federally-recognized tribes

within its borders to conduct a separate process for meaningful consultation with the tribes as part of the state section 1332 waiver public notice and comment process. The Departments explained they are of the view that allowing states to use the annual public forum for the dual purpose of soliciting public input on the state's proposed section 1332 waiver amendment request and on the progress of its approved waiver plan would create a more efficient process for both the state and the public to provide a meaningful level of input. Furthermore, the proposal would allow a state to explain to the public how the state's proposed section 1332 waiver amendment would interact with the state's approved waiver plan, and thus would be beneficial to the public in understanding the impact of the state's proposed waiver amendment.

The Departments proposed a similar Federal public notice and approval process for section 1332 waiver amendment requests as is outlined for new section 1332 waiver applications in 31 CFR 33.116 and 45 CFR 155.1316. In line with these requirements, the Departments proposed that following a determination that a state's section 1332 waiver application request for a section 1332 waiver is complete, the Secretaries will provide for a public notice and comment period that is sufficient to ensure a meaningful level of public input, and the comment period would generally be no less than 30 days. The Departments would make available through an HHS website the complete section 1332 waiver amendment request, information relating to how and where written comments may be submitted, and the timeframe during which comments will be accepted. Additionally, the Departments will make available public comments received on the section 1332 waiver amendment request during the Federal public notice and comment period. The Departments explained they are of the view that these proposals would increase transparency of the Federal review process and create a clear path for states and the Departments to determine if the information submitted is sufficient to continue review and when to start a Federal public comment period on the state's proposed waiver amendment. In addition, the Departments noted these proposals provide the public with a meaningful opportunity to provide input on a section 1332 waiver request in line with the intent of the statute.

c. Waiver Amendment Content

The Departments proposed that a state that wants to pursue a section 1332

waiver amendment request must furnish information and analysis regarding the state's proposed waiver amendment that is necessary to permit the Departments to evaluate the request. The proposed information and analysis are similar to the existing requirements for new section 1332 waiver applications.²⁰⁸ As such, the Departments proposed that a section 1332 waiver amendment request must include the following:

(1) A detailed description of the requested amendment, including the impact on the guardrails, and related changes to the section 1332 waiver program elements as applicable, including sufficient supporting documentation;

(2) An explanation and evidence of the process used by the state to ensure meaningful public input;

(3) Evidence of sufficient authority under state law(s) in order to meet the ACA section 1332(b)(2)(A) requirement for purposes of pursuing the section 1332 waiver amendment;

(4) An updated actuarial and/or economic analysis demonstrating how the section 1332 waiver, as amended, will meet the section 1332 statutory guardrails;

(5) An explanation of the estimated impact, if any, of the section 1332 waiver amendment on pass-through funding; and

(6) Any further requested information and/or analysis that is determined necessary by the Departments to evaluate the section 1332 waiver amendment.

For the required updated actuarial and/or economic analysis, the Departments proposed that such analysis must identify the "with waiver" impact of the requested amendment on the statutory guardrails. Such analysis would also be required to include a "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using data from recent experience, as well as a summary of and detailed projections of the change in the "with waiver" scenario. In addition, as described earlier, the Departments proposed that the analysis submitted by the state with its section 1332 waiver amendment request must demonstrate how the state's approved section 1332 waiver plan, combined with any proposed amendments, impacts the guardrails.

The Departments solicited comments on the proposals, including whether the proposed framework for section 1332 waiver amendment requests should be codified in regulation.

²⁰⁷ See 77 FR at 11706.

²⁰⁸ See 31 CFR 33.108 and 45 CFR 155.1308.

The following is a summary of the comments received and the Departments' responses to the waiver amendment request proposals and the proposed adoption of 31 CFR 33.130 and 45 CFR 155.1330.

Comment: The Departments received some comments on the proposals regarding waiver amendments. Commenters were supportive of the proposals overall and appreciated the clarification on what is required for a state with an approved waiver to request to make changes to the approved waiver. Several commenters sought further clarification on the definition of a waiver amendment under various scenarios. One commenter requested clarification regarding whether a state may have two separate section 1332 waivers or if any additional waiver request, while a state has an approved waiver, would be considered a waiver amendment. Another commenter relatedly asked if, for example, a state with an approved waiver plan were to seek both an extension and an amendment to its waiver plan, whether the state would be able to accomplish the two requests through one submission, rather than by making separate requests under 31 CFR 33.130 and 45 CFR 155.1330 for the amendment request and 31 CFR 33.132 and 45 CFR 155.1332 for the extension request. As another example, the commenter questioned whether a second waiver request submitted by a state with an approved waiver plan would automatically be considered an amendment request; or alternatively, whether the second waiver request would only be considered an amendment request if it was closely enough related to the state's approved waiver plan. Two commenters requested that the Departments minimize the burden on states seeking a section 1332 waiver amendment and only request from states the minimum documentation necessary to review the state's proposal. One commenter did not support the amendment provision because the commenter did not support the requirement for states to submit an amendment proposal at least 15 months prior to the waiver's implementation date, which in the commenter's view is too long and inflexible.

Response: The Departments appreciate these comments and look forward to working with states on potential amendments to approved waivers, extensions of approved waivers, and new waiver application requests. The Departments note that state waiver proposals may present novel approaches for providing coverage to a state's residents, such that by

nature, the outcomes may be difficult to predict and must be analyzed based on a state's specific proposal and circumstances. For example, as seen in each state's section 1332 waiver application, the required actuarial and economic analyses take into account various state-specific characteristics and data, such as historical and current information on premiums, target enrollee populations, market conditions, and other economic factors, in order to project the potential outcomes of implementing a section 1332 waiver under different scenarios. It would be difficult to ascertain whether a proposal is a waiver amendment, technical change to the existing waiver, or a new waiver application request without sufficient information and analysis. Accordingly, the Departments encourage states seeking to amend or otherwise modify a section 1332 waiver to contact the Departments early in their processes to discuss their plans and receive guidance on whether the request would be considered an amendment, a technical change, or a new waiver, taking into account their approved waiver plans and their proposals. This rulemaking provides a general framework for amendment requests, including the establishment of a definition for this key term, to provide states and other stakeholders with sufficient information to reasonably evaluate whether the state's proposal is an amendment. More specifically, as finalized, the term 'section 1332 waiver amendment' is defined as a change to a section 1332 waiver plan that is not otherwise allowable under the STCs of an approved waiver, a change that could impact any of the section 1332 statutory guardrails, or a change to the program design for an approved waiver. Regarding the specific questions related to whether a state could seek an amendment and an extension (defined later in this preamble) through a single submission, the Departments encourage states with approved waiver plans to discuss specific waiver proposals with the Departments, as that determination will depend on the details of the waiver proposal(s) and the state's approved waiver plan.

As discussed earlier in this preamble and in the proposed rule, the Departments will respond to the state and confirm whether the change requested is a section 1332 waiver amendment, as well as identify the information the state needs to submit in its waiver amendment request if the state's proposal is determined to be a waiver amendment. Depending on the complexity of the proposed waiver

amendment request, the scope of changes from the approved waiver plan, operational/technical changes, and implementation considerations, the Departments may impose requirements similar to those specified in 31 CFR 33.108(f) and 45 CFR 155.1308(f) for initial section 1332 waiver applications. In general, a waiver amendment request must include a detailed description of the requested amendment, including the impact on the guardrails; an explanation and evidence of the process used by the state to ensure meaningful public input; evidence of sufficient authority under state law to pursue the section 1332 waiver amendment; an updated actuarial and/or economic analysis; and an explanation of the estimated impact of the amendment on pass-through funding. This information is necessary to permit the Departments to evaluate the waiver amendment request. However, the Departments agree with certain commenters' concerns about minimizing the burden on states and will aim to request the minimum documentation and analysis necessary from states to review waiver amendment requests. For example, the Departments intend to use available data and resources, including the data and analysis in the periodic reports submitted by states with approved waivers under 31 CFR 33.124 and 45 CFR 155.1324, if appropriate, to minimize the burden on states. The Departments also clarify that the Departments are not requiring that states submit the letter of intent at least 15 months prior to the section 1332 waiver amendment's proposed implementation date, but that the Departments are encouraging states to follow that timeline and submit the letter of intent at least 15 months prior to the section 1332 waiver amendment's proposed implementation date to allow enough time for submission and review of the amendment request and to allow for an appropriate timeline for implementation of the already approved waiver and amendment, if approved.

After consideration of these comments, the Departments are finalizing the adoption of the waiver amendment framework along with clarifications outlined in this section of this preamble and the addition of 31 CFR 33.130 and 45 CFR 155.1330.

11. Waiver Extension (31 CFR 33.132 and 45 CFR 155.1332)

Section 1332(e) of the ACA provides that no section 1332 waiver may extend over a period of longer than 5 years unless the state requests continuation of its waiver, and such request shall be deemed granted unless the Departments,

within 90 days after the date of its submission, either deny such request in writing or inform the state in writing with respect to any additional information which is needed in order to make a final determination with respect to the request. Recognizing that several of the existing section 1332 waivers were approved in 2016 and 2017 to begin in plan years 2017 and 2018, respectively, the Departments proposed new regulations at 31 CFR 33.132 and 45 CFR 155.1332 to codify section 1332(e) of the ACA and also proposed, in preamble, the proposed framework for section 1332 waiver extensions. In response to previously received comments, the Departments acknowledged that information regarding section 1332 waiver amendments and renewals would be needed in the future²⁰⁹ and noted they received several inquiries from states on these topics. As such, the Departments proposed new regulations at 31 CFR 33.132 and 45 CFR 155.1332 to permit, but not require, states to submit a section 1332 waiver extension request to continue an approved waiver plan. The proposed new regulations also provide that an extension request shall be deemed granted unless the Secretaries, within 90 days after the date of the state's submission of a complete section 1332 waiver extension request, either deny such request in writing or inform the state in writing with respect to any additional information needed to make a final determination with respect to the request. The proposed rule also set forth, in preamble, a proposed procedural framework for submission and review of extension requests for approved section 1332 waiver plans. The Departments explained they are of the view that this additional information would help states with approved section 1332 waiver plans better plan for and prepare for potential extensions to their waiver plans. The Departments also noted they intend to provide information and details regarding the section 1332 waiver extension process in the STCs for an approved waiver plan. The proposals were intended to align with the extension request process outlined in recent STCs for states with approved section 1332 waivers.²¹⁰

The Departments proposed to define a section 1332 waiver extension as an extension of an approved waiver under the existing waiver terms. As detailed

further later in this section of this preamble, if a state wants to make changes to the existing terms of an approved section 1332 waiver, the proposed waiver amendment request framework would apply. The Departments proposed that states with approved section 1332 waivers that want to pursue a waiver extension would be required to inform the Departments if the state will apply for extension of its waiver at least one year prior to the waiver's end date. To request a section 1332 waiver extension, the Departments proposed that the state must submit a letter of intent in an electronic format to the Departments to notify them in writing of its intent to request a waiver extension of its approved waiver plan(s). The Departments would then review the state's letter of intent request. The Departments proposed that, within approximately 30 days of the Departments' receipt of the letter of intent, the Departments would respond to the state and confirm whether the extension request would be considered as an extension request or whether any changes requested result in the need for a waiver amendment request instead. The Departments would also identify the information the state needs to submit in its section 1332 waiver extension request. The Departments also proposed that section 1332 waiver extension requests must also be submitted in electronic format to the Departments, consistent with the format and manner requirements applicable to initial waiver applications under 31 CFR 33.108(a) and 45 CFR 155.1308(a).

The Departments also proposed that they may request an updated economic or actuarial analysis for the requested extension period in a section 1332 waiver extension request. Given that the Departments receive periodic reports from states with approved section 1332 waivers under 31 CFR 33.124 and 45 CFR 155.1324, in some circumstances the Departments may not need, and therefore, would not require full new analysis (as required under 31 CFR 33.108(f)(4) and 45 CFR 155.1308(f)(4) for initial section 1332 waiver applications) and instead may rely on the updated analyses provided as part of these periodic reports. In other instances, depending on the complexity of the section 1332 waiver and the extension request, the Departments may require additional data and information to be submitted to review the extension request.

The Departments proposed to evaluate the state's section 1332 waiver extension request and may approve the request if it meets the statutory

guardrails as defined in section 1332(b)(1)(A)–(D) and meets other applicable requirements. The Departments proposed that a state waiver extension request may be required to include the following information:

(1) Updated economic or actuarial analyses for the requested extension period in a format and manner specified by the Departments;

(2) Preliminary evaluation data and analysis from the existing section 1332 waiver program;

(3) Evidence of sufficient authority under state law(s) to meet the ACA section 1332(b)(2)(A) requirement for purposes of pursuing the requested extension;

(4) An explanation of the process followed by the state to ensure meaningful public input on the extension request at the state level; and

(5) Other information as requested by the Departments that is necessary to reach a decision on the requested extension.

As noted earlier in this preamble, the Departments would identify the specific information a state needs to include as part of its section 1332 waiver extension request in the response to the state's letter of intent. Further, the Departments proposed that the updated economic or actuarial analyses for the requested extension period would be in a format and manner specified by the Departments. The Departments would also rely on available data, such as the analyses provided as part of the periodic reports required under 31 CFR 33.124 and 45 CFR 155.1324, when evaluating a state's waiver extension request if appropriate.

The Departments also proposed that it would be permissible for a state to use its annual public forum required under 31 CFR 33.120(c) and 45 CFR 155.1320(c) for the dual purpose of soliciting public input on a proposed section 1332 waiver extension request and on the progress of its approved waiver plan. This policy proposal is in line with the flexibility the Departments permitted in the 2012 Final Rule²¹¹ to allow states to use Medicaid tribal consultation to also satisfy the requirements as set forth in 31 CFR 33.112(a)(2) and 45 CFR 155.1312(a)(2), that require a state with one or more federally-recognized tribes within its borders to conduct a separate process for meaningful consultation with such tribes as part of the state section 1332 waiver public notice and comment process. The Departments explained they are of the view that allowing states to use the annual public forum for the

²⁰⁹ See 77 FR 11700.

²¹⁰ For example, see STC 10 in New Hampshire's Approval Letter and STCs: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-NH-Approval-STCs.pdf>.

²¹¹ See 77 FR at 11706.

dual purpose of soliciting public input on an extension request and on the progress of its approved section 1332 waiver would create a more efficient process for both the state and for the public to provide a meaningful level of input.

The Departments proposed a similar Federal public notice and review process for a section 1332 waiver extension request as is outlined for new section 1332 waiver applications in 31 CFR 33.116 and 45 CFR 155.1316. The Departments proposed that the Departments would review a state's section 1332 waiver extension request and make a preliminary determination as to whether it is complete within approximately 30 days after it is submitted. In line with these requirements, the Departments proposed that after determining that the section 1332 waiver extension request is complete, the waiver extension request would be made public through the CMS website, and a 30-day Federal public comment period would commence while the extension request is under review. The Departments would make available through the CMS website the information relating to how and where written comments may be submitted and the timeframe during which comments will be accepted. Additionally, the Departments would make available public comments received on the section 1332 waiver amendment request during the Federal public notice and comment period. The determination that the section 1332 waiver extension request is complete would also mark the beginning of the 90-day clock outlined in section 1332(e) of the ACA for the Secretaries to deny or request more information regarding the continuation, or extension, of the state's approved waiver plan. If, after the extension request has been determined complete, the Departments find that content is missing, additional information is required, or the state needs to respond to public comments received during the Federal comment period, the Departments would notify the state and an additional review period would begin once the Departments received the requested information or responses from the state. The Departments proposed that this additional review period would be no longer than 90 days. The Departments explained they are of the view that these proposals increase transparency of the Federal review process and create a clear path for states and the Departments to determine if the information submitted is sufficient to continue review and when to start a

Federal public comment period. In addition, the Departments noted they are of the view that this proposal provides the public with a meaningful opportunity to provide input on a section 1332 waiver extension request in line with the intent of the statute.

The proposed section 1332 waiver extension request process would be separate from the waiver amendment framework described earlier in this rulemaking. A section 1332 waiver extension request under proposed 31 CFR 33.132 and 45 CFR 155.1332 would only be available for an extension of the existing terms of an approved waiver plans and would not be applicable if the state was seeking to make substantive changes to its approved waiver plan beyond a continuation of the term of the waiver. If a state also seeks to make substantive changes to its approved section 1332 waiver plan along with seeking an extension, the Departments would treat those changes as amendments and the framework outlined in this preamble for waiver amendment requests would apply.

The Departments solicited comments on these proposals, including whether the proposed framework for section 1332 waiver extension requests should be codified in regulation.

The following is a summary of the comments received and the Departments' responses to the waiver extension request proposals and the proposed adoption of 31 CFR 33.132 and 45 CFR 155.1332.

Comment: The Departments received some comments on the proposals regarding waiver extensions. Commenters were supportive of the proposals overall and appreciated the clarification on what is required for a state with an approved waiver to request an extension of the approved waiver. Several commenters requested clarification regarding whether a waiver could be extended with one or more amendments through one submission, rather than by making separate waiver extension and amendment requests.

Response: The Departments appreciate commenters' support. As finalized, a section 1332 waiver extension is defined as an extension of an approved waiver under the existing waiver terms. For example, if a state with an approved section 1332 reinsurance waiver wanted to extend a reinsurance program for an additional three years, but was not seeking to make any other changes beyond a technical change as allowable under the STCs, the request would be treated as a waiver extension request. Examples of allowable technical changes are revisions to a state's reinsurance

program parameters or a state's authorized funding source.²¹² Any changes to an approved waiver not otherwise allowable under the STCs would be considered an amendment. As explained earlier in this preamble regarding waiver amendments (31 CFR 33.130 and 45 CFR 155.1330), the Departments will analyze state waiver proposals, including amendment and extension requests, based on a state's specific proposals and circumstances. Accordingly, the Departments encourage states seeking to amend or extend a section 1332 waiver to contact the Departments early in their processes to discuss their plans and receive guidance on whether the request would be considered an amendment or an extension, as well as confirm the applicable requirements. In general, the Departments aim to work with states in a manner that provides clarity and transparency on the waiver extension and amendment process.

After consideration of these comments, the Departments are finalizing the adoption of the waiver extension framework along with clarifications outlined in this section of this preamble and the addition of 31 CFR 33.132 and 45 CFR 155.1332.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, the Departments are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that the Departments solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

HHS solicited public comment on each of these issues for the following sections of this preamble that contain ICRs.

²¹² Technical changes are changes that do not impact the guardrails or any obligations of the state or the Departments, such as changes to the state-approved program funding level or program parameters like altering the attachment point, cap, coinsurance rate, or eligible conditions.

A. ICRs Regarding Navigator Program Standards (§ 155.210)

The data collection requirements for FFE Navigator grantees are currently approved under OMB control 0938–1215/Expiration date: October 31, 2023 (Cooperative Agreement to Support Navigators in federally-facilitated Exchanges). The proposal to once again require FFE Navigators to provide consumers with information and assistance with regard to certain post-enrollment topics does not increase the number of reports that Navigator grantees are required to submit. Additionally, HHS does not anticipate changes to the data elements related to the expansion of required Navigator duties to be significant. HHS notes that since the 2020 Payment Notice made assistance with the topics at § 155.210(e)(9) permissible, but no longer required, many Navigator grantees have continued to report on these activities as part of their weekly, monthly, and quarterly metric reports to HHS. Therefore, HHS does not project the information collection burden to increase.

B. ICRs Regarding Segregation of Funds for Abortion Services (§ 156.280)

HHS is finalizing amendments to § 156.280(e)(2)(ii) to repeal the separate billing regulation governing payments for QHPs that offer coverage of abortion services for which Federal funds are prohibited. As finalized, HHS is reverting to and codifying in amended regulatory text at § 156.280(e)(2)(ii) the prior policy in the 2016 Payment Notice such that QHP issuers offering coverage of abortion services for which Federal funds are prohibited again have flexibility in selecting a method to comply with the separate payment requirement in section 1303 of the ACA. Acceptable methods for satisfying the separate payment requirement include sending the policy holder a single monthly invoice or bill that separately itemizes the premium amount for coverage of abortion services for which Federal funds are prohibited; sending the policy holder a separate monthly bill for these services; or sending the policy holder a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge. Repealing the separate billing regulation will remove the burden associated with the policy, as detailed below.

The 2019 Program Integrity Rule²¹³ estimated that the total one-time burden

to implement the separate billing regulation for the 94 issuers that were offering coverage for abortion services for which Federal funds are prohibited at the time of finalization would be 2,961,000 hours for a total cost of approximately \$385 million. HHS anticipated the one-time burden for the 3 State Exchanges that performed premium billing and payment processing and had QHP issuers that offered coverage for abortion services for which Federal funds are prohibited to be 94,500 hours for a total cost of approximately \$12.3 million. In the May 2020 IFC,²¹⁴ HHS reaffirmed these one-time estimates and anticipated that this one-time burden would still be incurred primarily in 2020, despite the 60-day delay to the implementation deadline.

The 2019 Program Integrity Rule also estimated ongoing annual costs for implementing the separate billing regulation. HHS estimated the total annual burden in 2020 for all 94 issuers would be 1,133,640 hours with an equivalent cost of approximately \$50.1 million. From 2021 onwards, HHS estimated the total annual burden for all 94 issuers to be approximately 2,267,280 hours with an associated cost of approximately \$100.2 million. HHS estimated that for the 3 State Exchanges performing premium billing and payment processing, the total annual burden would be approximately 36,180 hours with an equivalent cost of approximately \$1.6 million in 2020 and 72,360 hours with an associated cost of approximately \$3.2 million starting in 2021. HHS predicted in the May 2020 IFC that delaying the implementation of the deadline for the separate billing regulation by 60 days would result in a reduction to this annual burden in 2020 of 389,940 hours with an equivalent cost reduction of approximately \$17.4 million for all 97 issuers and State Exchanges performing premium billing and payment processing.

In addition, the Program Integrity Rule estimated that issuers and State Exchanges performing premium billing and payment processing would need to print and send approximately 1.82 million separate paper bills per month in 2020, incurring monthly costs of approximately \$91,200. The Program Integrity Rule estimated the total cost for all issuers and State Exchanges to be approximately \$547,225 in 2020. In 2021, HHS estimated that the annual cost for all issuers and State Exchanges to send separate paper bills would be approximately \$1,070,129 and that, in 2022, the annual cost would be approximately \$1,045,808. In the May

2020 IFC, HHS anticipated that delaying the implementation of the deadline for the separate billing regulation by 60 days would reduce the cost of printing separate bills in 2020 by approximately \$182,400.

As described in further detail in the preamble to § 156.280, the majority of commenters agreed with these burden estimates, citing significant concerns that the separate billing regulation was unduly burdensome to issuers, states, Exchanges, and consumers and could create consumer confusion, resulting in significant harm to consumers who inadvertently lose their coverage.

HHS disagrees with commenters contesting the validity of its burden estimates and suggesting that they are inflated. HHS again emphasizes that the 2019 Program Integrity Rule included a detailed account of the anticipated financial and operational burdens from the separate billing regulation, estimates which were based upon plan and premium data, actuarial estimates, public comments from issuers and states directly regulated by the separate billing policy, and consumer enrollment figures. Those burdens are discussed in further detail in sections III., “Collection of Information Requirements,” and IV., “Regulatory Impact Analysis,” of that rule, which explain from where such estimates are derived.

Some commenters noted that issuers have already incurred ongoing costs for printing and mailing, additional staffing, and reprogramming billing systems and that the separate billing regulation already resulted in increased burden for issuers and consumers, widespread confusion by consumers and other stakeholders, and an increase in frustration and confusion around grace periods and terminations. HHS acknowledges that some costs may have already been incurred by issuers and that the actual cost savings, especially for one-time IT related costs, may be lower than HHS estimates. Unfortunately, HHS does not have an estimate of costs already incurred by issuers and can only estimate savings going forward. HHS continues to believe the timing of the courts’ actions likely dissuaded most issuers from assuming further costly administrative and operational burdens required to build the separate billing policy into their billing and IT systems. Further, as the courts’ nationwide invalidation of the policy prevented HHS from requiring initial implementation of the separate billing regulation, the potential consumer confusion over payment obligations, which could have inadvertently led to non-payment of enrollee premium and subsequent

²¹³ 84 FR 71674 (December 27, 2019).

²¹⁴ 85 FR 27550 (May 8, 2020).

termination of consumer coverage, was also avoided.

Therefore, HHS believes repeal of the separate billing regulation removes the associated ICRs and the anticipated burden on QHP issuers and State Exchanges that perform premium billing and payment processing, which have not been approved by OMB. HHS will not pursue OMB approval of the ICRs associated with the repealed separate billing regulation (OMB control number: 0938–1358, Billing and Collection of the Separate Payment for Certain Abortion Services (CMS–10681)). As repeal of the separate billing regulation removes the associated ICRs with that regulation, the currently approved ICRs associated with issuer compliance with other longstanding requirements of § 156.280 in existence prior to finalization of the separate billing regulation apply and capture the associated burden with issuer compliance of § 156.280 (OMB control number: 0938–1156, Establishment of Exchanges and Qualified Health Plans (CMS–10400)). Those ICRs capture the estimated associated burden with issuer compliance under § 156.280(e)(5)(ii), which requires each QHP issuer offering coverage of abortion services for which Federal funding is prohibited to submit to the relevant state insurance commissioner a plan describing how the issuer will establish and maintain a separate payment account for any QHP that covers abortion services for which Federal funding is prohibited, and § 156.280(e)(5)(iii) which requires each QHP issuer to annually attest to compliance with section 1303 of the ACA and applicable regulations.

C. ICRs Regarding Section 1332 Waivers (31 CFR Part 33 and 45 CFR Part 155)

The Departments are finalizing modifications to the section 1332 waiver implementing regulations, including changes related to the interpretation of the statutory guardrails, the establishment of processes for section 1332 waiver amendment and extension requests, and the codification of new regulatory text related to pass-through funding for approved section 1332 waiver plans. In the proposed rule, the Departments discussed that the proposed policies and interpretations, if finalized, would supersede and replace prior finalized policies and interpretations. The Departments are also finalizing modifications to the regulations to set forth flexibilities in the public notice requirements and post award public participation requirements for section 1332 waivers during emergent situations, building off of the flexibilities provided during the

COVID–19 PHE. These altered requirements related to section 1332 waiver applications, compliance and monitoring, or evaluation do not impose any additional costs or burdens for states seeking waiver approval or those states with approved waiver plans that have not already been captured in prior burden estimates. Therefore, the Departments do not expect that implementing these provisions will significantly change the associated burden currently approved under OMB control number: 0938–1389/Expiration date: February 29, 2024.

VI. Regulatory Impact Analysis

A. Statement of Need

This rule implements revised FFE and SBE–FP user fees for the 2022 benefit year. It also repeals the Exchange DE option. The rule also includes changes related to the annual open enrollment period; Navigator program standards; and separate billing and segregation of funds for abortion services. In addition, it clarifies a provision related to special enrollment periods for enrollees that are newly eligible or ineligible for APTC, and establishes a monthly special enrollment period for qualified individuals who are eligible for APTC, and whose household income is expected to be no greater than 150 percent of the FPL during periods of time when APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP. Finally, relating to section 1332 waivers, it implements several changes, including the repeal of the incorporation of many policies and interpretations from the 2018 Guidance into the section 1332 waiver implementing regulations. This rule also finalizes proposed policies and interpretations governing section 1332 waivers that are consistent with providing more accessible and affordable health care through the individual and small group markets.

HHS is extending the annual open enrollment period to provide individuals with a longer opportunity to enroll in coverage, which will expand access to health insurance coverage, and HHS is codifying flexibility for State Exchanges that operate their own eligibility and enrollment platform to set annual open enrollment period end dates no earlier than December 15. Similarly, HHS is reinstituting prior requirements that FFE Navigators provide information and assistance with regard to certain post-enrollment topics, including helping consumers

understand basic concepts and rights related to health coverage and how to use it. In addition, HHS repeals the separate billing regulation at § 156.280(e)(2)(ii) that required individual market QHP issuers to send a separate bill for that portion of a policy holder's premium that is attributable to coverage for abortion services for which Federal funds are prohibited and to instruct such policy holders to pay for the separate bill in a separate transaction. This rule also reduces administrative burden on issuers, states, Exchanges, and consumers, as well as consumer confusion and unintended losses of coverage.

B. Overall Impact

HHS has 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. 96354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). 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). Based on HHS's estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is "economically significant" as measured by the \$100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, HHS has prepared a Regulatory Impact Analysis that to the best of its ability presents the costs and benefits of the rulemaking.

The provisions in this final rule will expand consumer access to affordable health care. The provisions in this final rule will extend the annual open enrollment period and codify flexibility for State Exchanges that operate their own eligibility and enrollment platform

to set annual open enrollment period end dates no earlier than December 15, expand Navigator duties, repeal the Exchange DE option, provide more funding for FFE Navigators and consumer outreach and education, and reduce administrative burden and confusion for consumers. These provisions will also reduce regulatory burden for states and administrative costs for Exchanges and issuers. Through the improvements in enrollment accessibility and increased affordability for consumers, these provisions will increase access to affordable health coverage.

The user fee rates in this final rule are higher than those previously finalized for 2022 in part 1 of the 2022 Payment Notice final rule,²¹⁵ which could increase premiums for consumers. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Proposed Rule Provisions and Accounting Table

In accordance with OMB Circular A-4, Table 1 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 allowing consumers to have continued access to coverage and health care and stabilizing premiums in the individual and small group health insurance markets, including in the Exchanges. HHS is unable to quantify all benefits and costs of this final rule. The effects in Table 1 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers and consumers.

TABLE 1—ACCOUNTING STATEMENT

Benefits:

Qualitative:

- Consumers will benefit from a longer annual open enrollment period, as they will have a greater opportunity to enroll in coverage.
- State Exchanges that operate their own eligibility and enrollment platform will benefit from flexibility to set annual open enrollment period end dates no earlier than December 15, as they will retain flexibility to determine the optimal annual open enrollment period length for their state.
- The special enrollment period clarification will benefit individuals who experience a decrease in household income that makes them newly eligible for an APTC amount of greater than zero dollars.
- Consumers will benefit from repeal of the separate billing regulation, as they will no longer be subject to the risk of confusing billing processes.
- APTC-eligible qualified individuals whose household income does not exceed 150 percent of the FPL will benefit from the new special enrollment period during periods of time when APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP, as they will have more opportunities to enroll in coverage throughout the year.

Costs:	Estimate	Year dollar	Discount rate (%)	Period covered
Annualized Monetized (\$/year)	– \$261.8 million	2020	7	2021–2025
	– \$259.0 million	2020	3	2021–2025

Quantitative:

- Reduction in costs to all issuers, states, State Exchanges performing premium billing and payment processing, Exchanges on the Federal platform, and consumers due to the separate billing regulation of approximately \$407.05 million in 2021, \$230.7 million in 2022, and \$229.3 million annually in 2023 and onwards. In addition to annual costs, the reduction in costs in 2021 includes the one-time implementation changes that issuers, states, States Exchanges performing premium billing and payment processing, and the Exchanges on the Federal platform would have incurred if the separate billing policy had been implemented in 2020. Because the separate billing policy was not implemented in 2020 due to courts invalidating the policy, these one-time costs could have been incurred in 2021, had the separate billing policy remained applicable.
- Increase in costs to Exchanges on the Federal platform of \$8.3 million annually to extend the annual open enrollment period to January 15.

Qualitative:

- Increased costs due to increases in provision of medical services (if health insurance enrollment increases).

Transfers:	Estimate	Year dollar	Discount rate (%)	Period covered
Annualized Monetized (\$/year)	\$480.9 million to \$1.2309 billion	2021	7	2022–2026
	\$481.5 million to \$1.2315 billion	2021	3	2022–2026

Quantitative:

²¹⁵ 86 FR 6138.

TABLE 1—ACCOUNTING STATEMENT—Continued

- Increase in transfers from issuers to Federal Government by approximately \$200 million in 2022 and approximately \$240 million in 2023 onwards due to changes in user fee rates and state transitions from FFEs to SBE-FPs or from SBE-FPs to State Exchanges.
- A potential 0.5 to 2 percent increase in premiums in 2022 and onwards as a result of the monthly special enrollment period for APTC-eligible qualified individuals whose household income does not exceed 150 percent of the FPL, during periods of time when APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP, with a corresponding potential increase in APTC/PTC annual outlays and decrease in income tax revenues of approximately \$250 million to \$1 billion.

This RIA expands upon the impact analyses of previous rules and utilizes the CBO analysis of the ACA's impact on Federal spending, revenue collection, and insurance enrollment. 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, HHS anticipates that the quantitative effects of the provisions in this rule are consistent with its previous estimates in the 2021 Payment Notice for the impacts associated with APTC, expanded consumer outreach and education and Navigators, and FFE user fee requirements.

1. Navigator Program Standards (§ 155.210)

HHS is amending § 155.210(e)(9) to reinstitute the requirement that FFE Navigators provide consumers with information and assistance with regard to certain post-enrollment topics. In FFEs, Navigators will continue to be permitted to undertake the Navigator duties specified in § 155.210(e)(9) until this provision becomes effective. FFE Navigators will be required to perform the Navigator duties specified in § 155.210(e)(9) beginning with Navigator grants awarded in 2022, including non-competing continuation awards. As finalized in this rule, prior to Navigator grant funding being awarded in FY 2022, FY 2021 Navigator grantees will be required to perform these duties beginning with the Navigator grant funding awarded in FY 2022 for the second 12-month budget period of the 36-month period of performance. To the extent Navigators awarded grant funding in FY 2021 are not already performing these duties under their year one project plans when this provision becomes effective, they can revise their project plans to incorporate performance of the duties specified in § 155.210(e)(9) as part of their non-competing continuation application for their FY 2022 funding.

These duties were previously required of Navigators in all Exchanges before the 2020 Payment Notice amended § 155.210(e)(9) and made assistance with these post-enrollment topics

permissible for FFE Navigators, but not required, beginning with FFE Navigator grants awarded in 2019. Despite no longer being required, the majority of FFE Navigators continue to provide information and assistance to consumers and report metrics on the post-enrollment topics outlined in § 155.210(e)(9). Additionally, by reinstituting the requirements at § 155.210(e)(9), HHS will be able to both require applicants to include plans for performing these post-enrollment activities as part of their annual applications for new or continued Navigator grant funding, as well as include Navigator assistance with these post-enrollment activities as part of their performance evaluations. All costs associated with reaching these consumers in FFEs would be considered allowable costs that would be covered by the Navigator grants for the FFEs and that may be drawn down as the grantee incurs such costs.

2. Exchange Direct Enrollment Option (§ 155.221(j))

HHS is removing § 155.221(j) and repealing the Exchange DE option, which established a process for states to use direct enrollment technology to transition to private-sector-focused enrollment pathways operated by QHP issuers, web-brokers, and agents and brokers, instead of or in addition to a centralized eligibility and enrollment website operated by an Exchange. HHS believes that repealing the Exchange DE option will have minimal impact on stakeholders at this time since no resources have been expended by states or HHS on implementing it. Any potential costs and burdens associated with the Exchange DE option would be eliminated. These include costs to develop consumer-facing enrollment functionality and meet eligibility application technical requirements, as well as to maintain back-end eligibility determination functionality and other back-end eligibility services; start-up and implementation costs to develop the appropriate privacy and security infrastructure and business controls; as well as costs related to ongoing oversight and monitoring of DE entities and maintaining the individual

interfaces and transactions with each DE entity. HHS also believes that repealing the Exchange DE option would mitigate potential negative downstream impacts, including consumer confusion and an increased uninsured and underinsured population. A more detailed discussion of potential impacts appears earlier in this preamble in the discussion of public comments on this provision.

3. Annual Open Enrollment Period Extension (§ 155.410(e))

HHS is extending the individual market annual open enrollment period from November 1 through January 15 for the 2022 coverage year and beyond, with a modification to codify flexibilities for State Exchanges not utilizing the Federal platform to choose an annual open enrollment period end date no earlier than December 15 and to adopt accelerated effective dates. HHS does not believe a significant impact on the Exchange risk pool will result from this change. Consumers will benefit from a longer annual open enrollment period without additional demand placed on them. A lengthened annual open enrollment period may result in an increase of \$8.3 million in technical infrastructure costs to the FFEs annually to support extended Cloud and application services associated with the extension. A lengthened annual open enrollment period may also lead to increased enrollments which could impose additional costs on Exchanges and enrollment assisters to conduct outreach and assist new consumers. However, this change could also reduce outreach costs on Exchanges and enrollment assisters by spreading out enrollments over a greater length of time, resulting in opportunities for efficiency and increased health coverage.

4. Monthly Special Enrollment Period for APTC-Eligible Qualified Individuals With a Household Income No Greater Than 150 Percent of the Federal Poverty Level Whose Applicable Taxpayer Has an Applicable Percentage of Zero (§ 155.420(d)(16))

HHS is finalizing the monthly special enrollment period for APTC eligible consumers with a projected annual

household income no greater than 150 percent of the FPL with coverage effective dates and other eligibility parameters as proposed, but is finalizing it so that the special enrollment period is only available during periods of time during which APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP. HHS is also finalizing that plan category limitations apply to this special enrollment period, and in consideration of concerns from certain commenters as further discussed in preamble, HHS is also finalizing § 155.420(a)(4)(ii)(D) with revisions to reflect that an enrollee who is adding a qualified individual or dependent through this special enrollment period may add the newly enrolling household member to their current QHP; or, change to a silver-level QHP and add their newly enrolling household member to this silver-level QHP; or, change to a silver-level QHP and enroll the newly enrolling qualified individual or dependent in a separate QHP. HHS believes that this modification is appropriate to provide clarity on options and limitations for enrollees whose household members newly enroll through this special enrollment period. In particular, HHS is finalizing that, while newly enrolling qualified individuals and dependents are not subject to plan category limitations, enrollees with a newly-enrolling dependent or other household member may not use the new monthly special enrollment period to change to a plan of any metal level to enroll together with their newly-enrolling household member, but can stay in the same plan or change to a silver plan to enroll together with the newly-enrolling household member.²¹⁶ Additionally, this special enrollment period will be available at the option of the Exchange, as proposed, in order to allow State Exchanges to decide whether to implement it based on their specific market dynamics, needs, and priorities. HHS is also finalizing that Exchanges on the Federal platform will implement this special enrollment period by providing qualified individuals who are eligible with a pathway to access it through the *HealthCare.gov* application.

To provide Exchanges with flexibility to prioritize ensuring that qualifying individuals are able to obtain coverage

through this special enrollment period quickly following plan selection, or to implement this special enrollment period in keeping with their current operations, HHS is adding a new paragraph at § 155.420(b)(2)(vii) to provide that the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the month following plan selection, at the option of the Exchange. Finally, HHS is adding a new paragraph at § 147.104(b)(2)(i)(G) to specify that issuers are not required to provide this special enrollment period in the individual market with respect to coverage offered outside of an Exchange, because eligibility for the special enrollment period is based on eligibility for APTC, and APTC cannot be applied to coverage that is not a QHP offered through an Exchange.²¹⁷

This special enrollment period availability will provide more opportunities for certain low-income APTC- and CSR-eligible consumers to take advantage of the financial assistance available to them. As discussed in the preamble for this rulemaking, HHS believes that the benefit to providing these opportunities outweighs adverse selection concerns. Further, HHS believes the risk of adverse selection is mitigated to some degree by most qualifying individuals having access to a premium-free silver plan with a 94 percent AV after application of APTC, because consumers eligible for a premium-free plan after application of APTC which, due to its 94 percent AV, covers such a significant portion of health care services, would likely already be enrolled if they were aware of their eligibility for such coverage. Additionally, HHS believes that those for whom this is the case are not likely to move in and out of coverage once they have enrolled, for example to end coverage once an immediate health care need is met, which may also limit some adverse selection risk. HHS also believes that applying plan category limitations to this special enrollment period will help to mitigate adverse selection because it will limit the ability of enrollees to change to a higher metal level plan based on a new health care need and then change back to a silver or bronze plan once the health issue is resolved. HHS also believes that enrollees who are interested in changing plans during the year through this special enrollment period will likely be deterred because such a change would generally mean they lose progress they have made toward meeting their

deductibles and other accumulators. However, HHS acknowledges that enrollees may still choose to enroll in a silver level plan that is more expensive than their zero-dollar option, and, with a monthly special enrollment period, could make this change during the plan year based on a difference in provider network or prescription drug formulary.

HHS requested comment on practices, including education and outreach, that could help ensure that consumers who are eligible for this special enrollment period enroll in the silver plan with a zero-dollar premium after application of APTC that is available to them. HHS also sought comment on the remaining risk for issuers; for example, on the extent to which there is risk related to consumers who become aware of the availability of the special enrollment period after they become sick and seek to enroll because they need medical care. Based on the possibility that consumers could enroll through the special enrollment period only after they need to use health care services, HHS sought comment on whether issuers may account for this risk through premium increases. HHS estimated a 0.5 to 2 percent increase in premiums when the enhanced APTC provisions of the ARP are in effect in states where this special enrollment period is implemented, due to increased adverse selection risk, resulting in an estimated \$250 million to \$1 billion increase in APTC/PTC outlays and decrease in income tax revenues nationwide, and HHS sought comment on this estimate.

HHS also sought comment on potential risk that individuals, including those who enroll in coverage due to a health event, later experience a household income change or change their primary place of residence such that they are no longer eligible for a silver plan with a zero-dollar premium, and that these individuals will end coverage at that point. Because this special enrollment period has the potential to introduce new adverse selection risk into the individual market, HHS also sought comment generally on the impact on premiums of this policy in Exchanges where it is implemented, and potential regulatory tools that could mitigate these risks.

For example, Exchanges that implement this special enrollment period could try to mitigate some risks with a robust outreach and education campaign to promote awareness of the special enrollment period. However, because the special enrollment period will be based on projected annual household income level, and Exchanges rely on applicants to report their most

²¹⁶ As noted in the proposed rule, this provision does not prevent enrollees who qualify for the new special enrollment period from changing to a plan of any category through a special enrollment period that provides this flexibility, including the special enrollment periods at § 155.420(d)(4), (8), (9), (10), (12), and (14).

²¹⁷ See IRC 36B(b)(2)(A), (c)(2)(A)(i).

up to date household income information, it may be difficult for Exchanges to assess which individuals might be eligible for outreach and education purposes and could make targeted marketing and outreach difficult. HHS also sought comment on practices that could help mitigate this challenge, and ways to improve outreach to low-income consumers more generally. Relatedly, HHS sought comment on how Exchanges could help to mitigate potential confusion on the part of stakeholders that provide enrollment assistance, such as HHS Navigator grantees, and agents and brokers. HHS sought comment on how Exchanges and stakeholders that provide enrollment assistance could develop effective outreach and education campaigns to target this population.

Finally, HHS requested comment on level of effort for Exchanges to implement this special enrollment period, especially within the amount of time required to make it available to consumers during the 2022 plan year.

The following is a summary of the comments received and HHS's responses to the comment solicitations related to the estimated impact of the monthly special enrollment period for APTC-eligible qualified individuals with a household income no greater than 150 percent of the FPL (§ 155.420(d)(16)).

Comment: As further discussed in preamble, some commenters supported the monthly special enrollment period and stated that the risk of adverse selection as a result of the policy would be limited due to the enhanced subsidy provisions of the ARP. Some of these commenters also stated that risk would be limited because younger and healthier individuals would be more likely to enroll when given additional opportunities to do so. As further discussed in preamble, many commenters also cited comparable state experiences as evidence of the low likelihood of adverse selection, such as the Massachusetts State Exchange's enrollment opportunity for individuals with a household income no higher than 300 percent of the FPL, and the ability of consumers up to 200 percent of the FPL to enroll in the Basic Health Program year-round in Minnesota and New York.

Some commenters added that State Exchange data on risk factors associated with enrollees who accessed coverage through a special enrollment period, including the special enrollment period that State Exchanges provided during the 2020 or 2021 plan years due to the COVID-19 pandemic, indicated that

these enrollees did not pose significant additional risk and in some cases were younger than the average age of enrollees who did not access coverage through the special enrollment period. One of these commenters asked that CMS analyze data on special enrollment period enrollees in states that use the *HealthCare.gov* platform, and suggested that such analysis would yield a similar result. Other commenters suggested that HHS could extend the special enrollment period to APTC-eligible individuals with household incomes up to 200 or 250 percent of the FPL with only a relatively small increase in adverse selection.

Response: HHS appreciates commenters' support of the monthly special enrollment period and agree that adverse selection will be mitigated during the period of enhanced subsidies due to the ARP. The goal of this policy is to increase access to affordable health care, consistent with E.O. 14009, and HHS appreciates comments stating that the monthly special enrollment period would increase the number of subsidized enrollees in the individual market. As further discussed in preamble, HHS also agrees that, in many cases, special enrollment periods may encourage consumers who are younger and healthier than average to enroll. Additionally, HHS acknowledges that some Exchanges that have expanded enrollment opportunities for consumers with a projected annual household income below a certain threshold have not experienced significant negative impacts from adverse selection. However, because HHS appreciates concerns that the risk of adverse selection may vary significantly based on market conditions specific to different Exchanges, and HHS's goal is also to achieve a balanced approach that takes into account these varying conditions as much as possible, HHS is finalizing this special enrollment period to limit it to be available only during periods of time when APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax year 2022, as provided by section 9661 of the ARP.

Comment: As noted in preamble, some commenters were concerned that the monthly special enrollment period would result in increased premiums, narrowed networks, fewer plan choices, and market instability due to adverse selection created by newly enrolling consumers but also, perhaps more significantly, by current enrollees using the special enrollment period to change plans mid-year based on provider network or other plan characteristics. Several of these commenters stated that

HHS's estimated increase in premiums of 0.5 to 2 percent was an underestimate of the true impact of this policy and argued that adverse selection would increase if the special enrollment period extends beyond the current expiration date of the ARP.

Several commenters agreed that adverse selection and related increases in individual health insurance premiums would vary significantly by state based on specific market conditions such as Medicaid expansion status. A few commenters voiced concerns that the HHS-operated risk adjustment methodology does not adequately compensate for individuals with partial-year or short-term enrollment. Several commenters, including some that supported the proposal, asked that CMS monitor the individual market for impacts of adverse selection, and one commenter asked us to engage in additional rulemaking if evidence of significant adverse selection is found. One commenter stated that this special enrollment period would increase enrollment and the increased costs would be overwhelmingly borne by the Federal Government in the form of increased APTC, but that these costs would be an appropriate use of Federal resources. However, other commenters voiced the concern that adverse selection would drive up rates and that these increases would disproportionately impact unsubsidized consumers.

Response: As further discussed in preamble, HHS acknowledges the potential impacts to premiums and adverse selection as a result of this special enrollment period and appreciates comments on its estimates of potential premium increases related to adverse selection. HHS also clarifies that HHS calculated this estimate based on currently available data and internal analyses, and based on the assumption that the proposed special enrollment period would only be available for coverage for periods of time during which APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero; in particular, during tax year 2022, as provided by section 9661 of the ARP. Based on this internal analysis and the balance of public comments, including those that cite other Exchanges' experiences with open-ended special enrollment periods, HHS continues to believe the risk of adverse selection with respect to this new special enrollment period is limited and is outweighed by the gains in coverage that would result from this special enrollment period.

Further, as discussed in preamble and the proposed rule, HHS believes that

applying plan category limitations to this special enrollment period will help to mitigate adverse selection, and HHS has updated the proposed regulatory text at § 155.420(a)(4)(ii)(D) to clarify that an enrollee who is adding a qualified individual or dependent may add the newly enrolling household member to their current QHP; or, change to a silver-level QHP and add their newly enrolling household member to this silver-level QHP; or, change to a silver-level QHP and enroll the newly enrolling qualified individual or dependent in a separate QHP. HHS notes that per the time limitation HHS is finalizing, the special enrollment period will be available only for coverage for periods of time during which APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, which is currently limited to tax year 2022, as provided by section 9661 of the ARP. HHS believes that the time-limited nature of this special enrollment period and the applicable plan category limitations will help to mitigate concerns about adverse selection, especially when combined with robust outreach and education efforts to maximize the number of qualifying individuals who gain coverage through the special enrollment period based on an understanding of its availability as opposed to enrolling due to an emerging health care need.

However, as also noted in preamble, HHS appreciates that adverse selection will likely vary across different Exchanges based on a variety of factors, such as whether a state has expanded its Medicaid program, and HHS will work with stakeholders to monitor individual health insurance markets while the special enrollment period is in place to track potential adverse selection impacts of the special enrollment period, as well as access to coverage for higher-income individuals, in particular those who do not qualify for a monthly APTC payment of more than zero dollars, and to consider possible approaches to address any issues that arise.

Last, as discussed in this preamble, the HHS-operated risk adjustment methodology added enrollment duration factors to the adult risk adjustment models starting with the 2017 benefit year. These enrollment duration factors are used in the calculation of adult enrollee risk scores under the state payment transfer formula to account for additional risk associated with enrollees with partial-year enrollment. They do so through a set of 11 enrollment duration binary indicator variables that signify that an enrollee had exactly one to 11

months of enrollment in a given plan. The value of these indicators decreases monotonically from one to 11 months, reflecting the increased annualized costs associated with fewer months of enrollment. Adult enrollees who enrolled during this special enrollment period will receive the applicable enrollment duration factor in the risk score calculation. While HHS continues to evaluate the current enrollment duration factors, HHS generally disagrees with comments asserting the risk adjustment methodology does not adequately address partial year enrollees.

Comment: As also discussed in preamble, some commenters stated the concern that issuers had not had time to incorporate adverse selection risk related to the proposed special enrollment period into their rates for the 2022 plan year. However, no commenters recommended giving issuers an additional opportunity to adjust rates before the 2022 plan year. Several commenters requested that HHS delay making the proposed special enrollment period available until the 2023 plan year if HHS finalized the proposal, in order to provide issuers with adequate time to incorporate related risk into their rates.

Response: Based on HHS's determination that consumers who are eligible for free or very low-cost coverage provided by enhanced APTC through the ARP will benefit from additional opportunities to enroll in Exchange coverage while this enhanced assistance is in place, HHS is finalizing the special enrollment period to be available for the 2022 plan year, and to be limited to provide coverage for periods of time during which APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, including tax year 2022, as provided by section 9661 of the ARP.

5. Clarification of Special Enrollment Periods for Enrollees Who Are Newly Eligible or Newly Ineligible for Advance Payments of the Premium Tax Credit (§ 155.420(f))

HHS is finalizing new language to clarify, for purposes of the special enrollment period rules at § 155.420, that a qualified individual, enrollee, or his or her dependent, who qualifies for APTC because they meet the criteria at § 155.305(f), but who qualifies for a maximum APTC amount of zero dollars, is not considered APTC eligible, even when they have previously been APTC ineligible for another reason, such as having other MEC. HHS believes that the special enrollment period rules that

reference APTC eligibility at § 155.420(d)(6) could have permitted inconsistent interpretations of what it means to be newly eligible or ineligible for APTC when an individual is found to be eligible generally to receive APTC, but for a specific APTC amount of zero dollars. HHS believes that this clarification will help ensure that the special enrollment periods at § 155.420(d)(6) are available to individuals as intended: Those determined to be newly eligible for an APTC amount greater than zero dollars.

HHS believes that this change will not be relevant to a significant number of individuals in Exchanges on the Federal platform, but that for the reasons described in preamble, it will be important in light of the removal of the upper APTC eligibility limit on household income at 400 percent of the FPL for taxable years 2021 and 2022 under the ARP.²¹⁸ More specifically, this definition makes clear that an individual who qualifies for a maximum APTC amount of zero dollars would qualify for a special enrollment period per § 155.420(d)(6)(i) or (ii) if, later in the plan year, they became newly eligible for an APTC amount greater than zero dollars based on a decrease in their household income. This clarification may be helpful for any individual who experiences a decrease in household income that makes them newly eligible for an APTC amount of greater than zero dollars.

As of March 1, 2021 (prior to the passage of the ARP), approximately 7.25 million enrollees through Exchanges on the Federal platform were APTC eligible, but only 36,000 (or 0.5 percent) were APTC eligible with a maximum APTC amount of zero dollars. However, just under 119,000 enrollees through Exchanges on the Federal platform reported a household income that was greater than 400 percent of the FPL. HHS analysis indicated that roughly 35,000 of this greater than 400 percent FPL population would automatically be considered APTC eligible with a maximum APTC amount of zero dollars once the 400 percent FPL limit on household income had been removed and these enrollees were no longer considered APTC ineligible simply by virtue of exceeding that limit, doubling the number of potentially impacted enrollees through Exchanges on the Federal platform even before to the passage of the ARP. Additionally, as of March 1, 2021, HHS identified roughly 501,000 enrollees that did not report any household income on their application; some of these enrollees may

²¹⁸ Public Law 117–2.

also be newly eligible for APTC under the new rules. After passage of the ARP and CMS's removal of the 400 percent FPL limit on household income regarding qualifying individuals applying for coverage through an Exchange on the Federal platform, the number of enrollees who did not provide household income decreased slightly, to just under 472,000, and the number of enrollees reporting a household income greater than 400 percent of the FPL has increased to over 191,000. The number of enrollees eligible for a maximum APTC amount of zero dollars has also increased slightly, to just under 42,000 individuals. More recently, the number of enrollees who did not provide household income decreased further, to just under 458,000, and the number of enrollees reporting a household income greater than 400 percent of the FPL has increased to over 280,000. The number of enrollees eligible for a maximum APTC amount of zero dollars has also increased, to just over 51,000 individuals.²¹⁹ As noted in the proposed rule, HHS expects these trends continue during 2022 in Exchanges on the Federal platform and likely in other State Exchanges, as well, making this clarification especially relevant at that time.

HHS sought comment on the proposal, including from State Exchanges regarding whether this definition of APTC eligibility reflects their current implementation of the special enrollment period qualifying events per § 155.420(d)(6), and if not, whether there are policy concerns about this clarification, or concerns about the burden of making related changes to State Exchanges' operations. HHS also sought comment on whether any group of individuals who may qualify for one or more of the special enrollment periods at § 155.420(d)(6) could be harmed by this clarification, and if so, how such harm could be mitigated.

The summary of the comments received and HHS's responses to the comment solicitations related to the clarification of special enrollment period for enrollees who are newly eligible or newly ineligible for advance payments of the premium tax credit (§ 155.420(f)) appears in that preamble section earlier in this rule.

²¹⁹ Figures repeated here that were also included in the proposed rule were drawn from internal CMS analysis as of late May 2021, almost 2 months after CMS updated *HealthCare.gov* to reflect the removal of the 400 percent FPL limit on household income on applicants applying for coverage with APTC. New figures are from internal CMS analysis as of late August 2021.

6. FFE and SBE–FP User Fees (§ 156.50)

HHS is finalizing an increased FFE user fee rate of 2.75 percent for the 2022 benefit year, which is higher than the 2.25 percent FFE user fee rate finalized in part 1 of the 2022 Payment Notice. HHS is also increasing the SBE–FP user fee rate to 2.25 percent for the 2022 benefit year from the 1.75 percent SBE–FP user fee rate finalized in part 1 of the 2022 Payment Notice final rule.²²⁰ Based on HHS's estimated costs, enrollment (including anticipated transitions of states from the FFE and SBE–FP models to either the SBE–FP or State Exchange models), premiums for the 2021 and 2022 benefit years, and user fee rates, HHS expects transfers from issuers to Federal Government to be increased by approximately \$200 million in plan year 2022.

HHS is repealing the 2023 benefit year user fee rate for the Exchange DE option in FFE and SBE–FP states, which was finalized in part 1 of the 2022 Payment Notice final rule. No state entity has approached HHS to consider this option. Since this option has not been implemented in any state, HHS does not expect any changes to user fee transfers from issuers to the Federal Government due to this rescission.

7. Segregation of Funds for Abortion Services (§ 156.280)

HHS is amending the separate billing regulation at § 156.280(e)(2)(ii) that governs payments for QHPs that provide coverage of abortion services for which Federal funds are prohibited. As finalized, HHS reverts to codifies prior policy that allowed QHP issuers offering coverage of such abortion services flexibility in selecting a method to comply with the separate payment requirement in section 1303 of the ACA. As finalized, the acceptable methods for satisfying the separate payment requirement include sending the policy holder a single monthly invoice or bill that separately itemizes the premium amount for coverage of such abortion services; sending the policy holder a separate monthly bill for these services; or sending the policy holder a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services and specify the charge.

The 2019 Program Integrity Rule extensively detailed the anticipated financial and operational burdens from the separate billing regulation. HHS continues to believe removal of the separate billing regulation will remove the significant burden associated with

the separate billing regulation. Those burdens included costly estimates for issuer implementation of the technical build to implement the necessary system changes to support separate billing and receipt of separate payments, which would require significant changes to current billing practice and pose increased challenges for some states and issuers given the mid-plan year implementation timeline. These activities included planning, assessment, budgeting, contracting, and building and testing their systems; as well as one-time changes such as billing-related outreach and call center training. The burdens also included ongoing costs related to sending a separate bill, such as those related to identifying impacted enrollees, ensuring billing accuracy, reconciliation, quality assurance, record keeping, document retention, support for enrollees who enter grace periods for non-payments, customer service, outreach, and compliance. Issuers would also be expected to assume annual materials costs related to printing of and sending the separate bill. HHS anticipated that State Exchanges would experience increased burden associated with one-time technical changes such as updating online payment portals to accept separate payments and updating enrollment materials and notices that reference binder payments, and ongoing costs related to increased customer service, outreach, and compliance.

HHS also stated in the 2019 Program Integrity Rule that QHP issuers were likely to consider these new costs when setting actuarially sound rates and that this would likely lead to higher premiums for enrollees. Specifically, HHS estimated there would be an approximate premium impact of up to 1.0 percent in plan year 2021 and each year thereafter in states with QHP issuers offering coverage of abortion services for which Federal funds are prohibited. HHS also estimated that enrollment would be slightly reduced in the impacted states as a result of the increase to premiums. In plan year 2021 and each year after, HHS estimated that APTC amounts would increase up to \$146 million when premium rates reflect the projected additional administrative and operational expense burdens.

HHS also projected in the 2019 Program Integrity Rule that the FFEs would incur additional costs due to one-time technical changes and increased call volumes and additional customer service efforts. HHS estimated that the FFEs would incur a one-time cost of \$750,000 in 2020 and ongoing annual costs of approximately \$400,000 in

²²⁰ 86 FR 6138.

2020, \$800,000 in 2021, \$600,000 in 2022, and \$400,000 in 2023 onwards to implement the separate billing policy.

HHS also anticipated that all impacted State Exchanges would incur one-time costs of \$9 million in 2020 for necessary technical changes such as updating online payment portals to accept separate payments and updating enrollment materials. In addition, HHS estimated that State Exchanges would incur ongoing annual costs associated with increased customer service, outreach, and compliance totaling \$2.4 million in 2020, \$4.8 million in 2021, \$3.6 million in 2022, and \$2.4 million in 2023 onwards for all impacted State Exchanges.

HHS also anticipated increased costs to consumers for the time required to read and understand the separate bills and seek help from customer service, and additional time to read and send separate payments in subsequent months. For the estimated 2 million policy holders in plans offering coverage of abortion services for which Federal funds are prohibited, the Program Integrity Rule estimated a total annual cost for of 2.9 million hours in 2020 with an associated annual cost of \$35.5 million. HHS decreased this estimated burden slightly in the May 2020 IFC to account for a burden reduction of approximately 337,793 hours with an equivalent cost savings of approximately \$4.2 million. For subsequent years, HHS estimated in the 2019 Program Integrity Rule that the annual enrollee burden would be approximately 2 million hours with an associated annual cost of approximately \$25.1 million.

In total, the projected burden to all issuers, states, State Exchanges performing premium billing and payment processing, the FFEs, and consumers due to the separate billing policy regulation totaled \$546.1 million in 2020, \$232.1 million in 2021, \$230.7 million in 2022, and \$229.3 million annually in 2023 and onwards.

HHS also believes the consumer confusion and new logistical obstacles due to the separate billing regulation would disproportionately harm and burden communities that already face barriers to accessing care and that any potential coverage losses caused by the separate billing regulation could further exacerbate existing health disparities and jeopardize health outcomes. Further, issuers dropping coverage of abortion services for which Federal funds are prohibited as a result of the burden associated with the separate billing regulation could transfer out-of-pocket costs for this coverage to enrollees, which may disproportionately

impact low-income women who already face barriers to accessing quality health care.

Comment: Commenters supporting repeal of the separate billing regulation and codification of the prior policy confirmed these estimates and expressed support for removal of an onerous billing requirement on issuers, states, Exchanges, and consumers. Commenters stated that issuers would have had to redesign their billing systems for only a small portion of their business in the individual market Exchanges. Commenters agreed that the separate billing regulation would have imposed expensive IT changes on issuers and states, requiring creation of a billing system only for individual Exchanges and not for products sold in any other market. Commenters also agreed that the separate billing regulation would have required costly changes to other issuer operations such as invoice processing, collections, customer service support, and other transactions with Exchanges. Commenters also agreed there would be added administrative costs of mailing separate bills in separate envelopes and collecting separate payments. Some commenters noted that issuers have already incurred ongoing costs for printing and mailing, additional staffing, and reprogramming billing systems and that the separate billing regulation already resulted in increased burden for issuers and consumers, widespread confusion by consumers and other stakeholders, and an increase in frustration and confusion around grace periods and terminations. Commenters also expressed concern that the highest costs from the separate billing regulation would have been concentrated in states that require abortion coverage.

For example, one commenter noted that many of its QHPs that offer abortion coverage for which Federal funding is prohibited are in states where the State Exchange operationalizes the premium billing and collections process on behalf of issuers, while others directly bill consumers. This commenter noted that for issuers operating in states that operationalize the billing and collections themselves, issuers expected that there would be an additional assessment to cover the costs to the state, which will ultimately be factored into premiums, as the 2019 Program Integrity Rule acknowledged. In other states, including those where abortion coverage for which Federal funding is prohibited is mandatory, the commenter explained that issuers would have been tasked with the complete operational and financial burden. This commenter

asserted that the separate billing regulation therefore conflicted with the common goal among QHPs to keep costs and premiums low in order to provide affordable care for low-income and vulnerable populations.

Commenters also asserted that the separate billing regulation seemed to serve no discernible purpose beyond the introduction of easily-avoidable administrative complexity for health plans and red tape for consumers. As such, commenters believe that the separate billing regulation would have caused issuers to stop covering abortion services for which Federal funding is prohibited in states where such coverage is not mandated. Commenters agreed that, if issuers were to drop such abortion coverage, the costs would be transferred to consumers and would likely disproportionately impact low-income women that already face barriers to accessing health care services. Commenters also noted that the burden would have been particularly significant in states that require individual market QHP coverage of abortion because, in such states, every QHP policy holder would have received two separate bills and been instructed to pay those bills in two separate transactions. Commenters assert that this would have caused significant harm to individual market enrollees and that implementation costs for issuers would have further harmed consumers by causing their premiums to increase. Commenters again agreed that these negative impacts, including the widespread consumer confusion that could result in an increased number of consumers losing their health coverage, would have had a disproportionate impact on the state's most vulnerable residents.

Commenters objecting to repeal of the separate billing regulation argued that HHS has not shown how repeal of the separate billing regulation and codification of the prior policy will add a financial benefit to either consumers or insurers that outweighs the harm caused to consumer transparency, conscience protections, and statutory compliance with section 1303. Objecting commenters also broadly criticized HHS's cost estimates for the burden associated with the separate billing regulation, arguing that HHS failed to consider important factors, explore sufficient data, and make necessary estimates. Objecting commenters also alleged that, regardless of the extent of burden associated with the separate billing regulations on issuers, states, Exchanges, and consumers, that any such burden is not unreasonable, but necessary to ensure compliance with section 1303 of the

ACA. Commenters also asserted that HHS did not provide sufficient evidence that certain groups of people are more likely to be impacted by the separate billing regulation than others and that, in any event, such arguments cannot justify violating the separate billing requirement that commenters argue is expressly required under section 1303 of the ACA.

Commenters objecting to repeal of the separate billing regulation asserted that the cost estimates fail to address or take into account recent changes in the law made by the ARP. Commenters stated that millions of Americans are newly eligible for zero-dollar coverage under ARP but that, in states where all or most ACA individual market plans cover abortion for which Federal funding is prohibited, consumers will not be able to purchase a zero-dollar premium plan because of section 1303's funding restrictions. Commenters therefore argued that individuals in such situations are already paying, in effect, a "separate bill" for that coverage and would not face additional burdens established by the separate billing regulation. Commenters raising this objection asked HHS to explain how the Department will enforce section 1303's funding restrictions for otherwise zero-premium Exchange plans and to provide a state-by-state analysis of the effects of the proposed rule.

Response: HHS agrees with commenters concerns regarding the costs and burdens the separate billing policy would have imposed on stakeholders. As raised by some commenters, HHS also acknowledges that some costs may have already been incurred by issuers and that the actual cost savings, especially for one-time IT related costs, may be lower than HHS estimates. Unfortunately, HHS does not have an estimate of costs already incurred by issuers and can only estimate savings going forward. HHS disagrees with comments contesting the validity of these burden estimates. Further, as the courts' nationwide invalidation of the policy prevented HHS from requiring initial implementation of the separate billing regulation, the potential consumer confusion over payment obligations, which could have inadvertently led to non-payment of enrollee premium and subsequent termination of consumer coverage, was also avoided.

HHS acknowledges that consumers who live in states where premiums for Exchange coverage cannot be fully paid for with APTC, such as states that require coverage of abortion services for which Federal funding is prohibited, will not have access to a silver plan

with a zero-dollar premium, as further explained in the preamble to § 155.420(d)(16) of the proposed rule.²²¹ However, HHS also notes that individual market QHP issuers covering abortion services for which Federal funds are prohibited offering coverage to consumers who qualify for zero-dollar premium plans are still required to comply with section 1303 of the ACA and all applicable requirements codified at § 156.280. HHS also notes that the ARP was enacted in 2021, and therefore, the consumer cost and burden estimates in each respective rule regarding the separate billing regulation were based on the estimated number of all consumers enrolled in QHPs offering coverage for abortion and are reflective of the anticipated burden at that time.

The 2019 Program Integrity Rule included a detailed account of the anticipated financial and operational burdens from the separate billing regulation, estimates which were based upon plan and premium data, actuarial estimates, public comments from issuers and states directly regulated by the separate billing regulation, and consumer enrollment figures. Those burdens are discussed in further detail in sections III., "Collection of Information Requirements," and IV., "Regulatory Impact Analysis," of that rule, which explain from where such estimates are derived. As explained in more detail in the preamble to § 156.280, HHS also agrees with commenters that the consumer confusion and new logistical obstacles from the separate billing regulation would disproportionately burden communities who already face barriers to accessing care.

Upon reassessing the separate billing regulation, and in light of the legal developments, HHS no longer sees a discernible benefit to requiring separate billing that would be sufficient to outweigh its burdens. Section 1303 does not specify the method a QHP issuer must use to collect the separate payment²²² and multiple Federal district courts have already invalidated the separate billing regulation, preventing HHS from requiring its implementation.²²³ HHS is therefore finalizing a policy that allows issuers to satisfy the separate payment requirement through methods consistent with section 1303 of the ACA; that

imposes no more burden on issuers, states, Exchanges, and consumers than is necessary; and that removes unreasonable barriers to obtaining appropriate medical care. HHS anticipates repeal of the separate billing regulation will remove the associated burdens to issuers, states, Exchanges, and consumers by allowing issuers to continue the billing practices and collection methods previously adopted and relied upon since publication of the 2016 Payment Notice.

8. Section 1332 Waivers

In this rule, the Departments are finalizing modifications to the section 1332 waiver implementing regulations, including the adoption of new policies and interpretations of the statutory guardrails. The Departments also finalize new processes and procedures for amendment and extension requests for approved section 1332 waiver plans. As outlined in this final rule, the policies and interpretations in this rule will supersede and replace prior finalized policies and interpretations. The Departments are also modifying these regulations to set forth flexibilities in the public notice requirements and post award public participation requirements for section 1332 waivers during future emergent situations. However, this rule does not alter any of the requirements related to state innovation waiver applications, compliance and monitoring, or evaluation in a way that would create any additional costs or burdens for states submitting proposed waiver applications or those states with approved waiver plans that has not already been captured in prior burden estimates. As such, the Departments are of the view that both states with approved section 1332 waivers and states that are considering section 1332 waivers would continue to comply with the requirements noted earlier without creating any additional costs or burdens that have not already been accounted for in prior impact estimates of benefits and costs. The Departments anticipate that implementing these provisions would not significantly change the associated burden currently approved under OMB control number: 0938–1389/Expiration date: February 29, 2024. The Departments are of the view that section 1332 waivers could help increase state innovation, which in turn could lead to more affordable health coverage for individuals and families in states that consider implementing a section 1332 waiver program.

²²¹ 86 FR 35156.

²²² 84 FR 71674, 71683.

²²³ *Planned Parenthood of Maryland, Inc. v. Azar*, No. CV CCB–20–00361 (D. Md. July 10, 2020); 5 U.S.C. 706; *California v. U.S. Dep't of Health & Hum. Servs.*, 473 F. Supp. 3d 992 (N.D. Cal. July 20, 2020); *Washington v. Azar*, 461 F. Supp. 3d 1016 (E.D. Wash. 2020).

9. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, HHS 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, HHS assumes that the total number of unique commenters on part three of the 2022 Payment Notice proposed rule will be the number of reviewers of this final rule. HHS acknowledges that this 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, HHS believed that the number of commenters on part three of the 2022 Payment Notice proposed rule, in addition to the number of states and issuers in the individual, small and large group markets nationwide, would be a fair estimate of the number of reviewers of the final rule. HHS welcomed any comments on the approach in estimating the number of entities which will review the proposed rule.

HHS also recognized that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of this estimate, HHS assumes that each reviewer reads approximately 50 percent of the rule. HHS sought comments on this assumption.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11-9111), HHS estimates that the cost of reviewing this rule is \$114.24 per hour, including overhead and fringe benefits.²²⁴ Assuming an average reading speed, HHS estimates that it would take approximately 1 hour for the staff to review half of this final rule. HHS assumes 652 entities will review this final rule. For each entity that reviews the rule, the estimated cost is approximately \$114.24 (1 hour × \$114.24). Therefore, HHS estimates that the total cost of reviewing this regulation is approximately \$74,588.80 (\$114.24 × 652 reviewers).

D. Regulatory Alternatives Considered

In developing the policies contained in this final rule, HHS considered numerous alternatives to the provisions. Below HHS discusses the key regulatory alternatives that HHS considered.

HHS considered taking no action related to adding a new paragraph at § 155.420(d)(16), to provide a monthly special enrollment period for qualified individuals or enrollees, or the dependent of a qualified individual or enrollee, who are eligible for APTC and whose household income is expected to be no greater than 150 percent of the FPL. However, HHS believes that many consumers will benefit from having additional opportunities to enroll in low-cost Exchange coverage, and that those who will be eligible for this special enrollment period and who do not enroll during the annual open enrollment period are likely to have been unaware of their option to enroll in a plan with no monthly premium through the Exchange, after application of APTC. HHS also considered whether, if HHS were to provide this special enrollment period, whether it should be limited to periods of time when enhanced APTC benefits were also available, such as those provided by the section 9661 of the ARP. Based on public comments and in order to help mitigate adverse selection concerns, HHS is limiting availability of this special enrollment period to periods of time when APTC benefits are available such that the applicable taxpayers' applicable percentage is set at zero, such as during tax years 2021 and 2022, as provided by section 9661 of the ARP. Finally, HHS also considered and received comment on other strategies to help individuals who may benefit from the proposed special enrollment period, some of whom may qualify for another existing special enrollment period or could benefit from assistance with transitioning between Medicaid and Exchange coverage. HHS will continue to consider innovative and thoughtful steps that HHS and Exchanges may take to assist consumers with transitions between different coverage types and help them to maintain continuous coverage. However, HHS is also finalizing the proposed special enrollment period to maximize opportunities for consumers to enroll in free or low-cost coverage of which they may not be aware.

HHS considered taking no action related to its clarification, for purposes of the special enrollment period rules at § 155.420, that a qualified individual, enrollee, or his or her dependent who qualifies for APTC because they meet the criteria at § 155.305(f), but who qualifies for a maximum APTC amount of zero dollars, is not considered APTC eligible. However, HHS is finalizing as proposed because, in consideration of generally supportive public comments,

HHS continues to believe that consumers and other stakeholders will benefit from this clarification because it improves transparency of Exchanges' implementation of the special enrollment period qualifying events provided at § 155.420(d)(6).

HHS considered restoring user fee rates to their 2021 levels at 3 percent and 2.5 percent of total monthly premium for issuers in the FFEs and SBE-FPs, respectively. However, based on HHS's analysis of estimated 2022 enrollment, premiums, and contract costs, HHS determined that this increase would be unnecessary to finance the Exchange essential functions.

Regarding the section 1332 waiver provisions in this rule, the Departments considered rescinding the 2018 Guidance and the regulatory updates and policies finalized in part 1 of the 2022 Payment Notice final rule such that the Departments would rely on the statute for review and approval of section 1332 waiver applications. The Departments did not choose this option because not outlining policies, interpretations, and standards to help explain the section 1332 program requirements and the Departments' interpretations thereof would lead to uncertainty for states considering section 1332 waiver applications. The Departments also considered codifying the policies and interpretations in the 2015 Guidance in regulation, but determined finalizing new policies and interpretations (some of which align with previous guidance and rulemaking) was the clearest way to explain the requirements for submission and approval of section 1332 waivers.

E. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare a final regulatory flexibility analysis to describe the impact of the final 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 considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities experience a change in revenues of more than 3 to 5 percent.

²²⁴ https://www.bls.gov/oes/current/oes_nat.htm.

In this rule, HHS finalizes revised 2022 user fee rates, which will impact issuer rate setting. HHS believes that health insurance issuers and group health plans would 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 \$41.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$35 million or less.²²⁵ HHS believes that few, if any, insurance issuers underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report²²⁶ submissions for the 2019 MLR reporting year, approximately 77 out of 479 issuers of health insurance coverage nationwide had total premium revenue of \$41.5 million or less. This estimate may overstate the actual number of small health insurance issuers that may be affected, since over 67 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 will result in their revenues exceeding \$41.5 million. The user fee rates finalized in this rule are lower than the 2021 benefit year user fee rates by 0.25 percent, and these new rates are higher than the previously finalized 2022 benefit year user fee rates by 0.5 percent. Therefore, these user fee rates will only impact premium revenue for these issuers by approximately 0.25 percent, since no issuer has effectuated payments under the previously finalized user fee rates, and this impact is below HHS's 3 to 5 percent significance threshold stated earlier.

In this final rule, HHS also codifies a new monthly special enrollment period for certain APTC-eligible individuals. Because this special enrollment period has the potential to introduce new adverse selection risk into the individual market, HHS sought comment in the RIA on the impact on premiums of this policy in Exchanges where it is implemented. HHS estimates that this policy could result in an increase in premiums of 0.5 to 2 percent when the enhanced APTC provisions of

the ARP are in effect, and this impact is below HHS's 3 to 5 percent significance threshold stated earlier in this preamble.

In addition, the other provisions in this rule will either reduce costs or have no cost impact. Therefore, HHS does not expect the provisions of this rule to affect a substantial number of small entities. HHS does not believe that this threshold will be reached by the requirements in this final rule. Therefore, the Secretary of HHS has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires HHS to prepare a regulatory impact analysis in certain cases if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, HHS defines a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the Act, HHS has determined that this final rule would not affect small rural hospitals, as the policies finalized in this rule impact consumer assisters, Exchanges, states, issuers, and consumers, but do not directly pertain to providers or facilities. Therefore, the Secretary of HHS has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately \$158 million. Although HHS has not been able to quantify all costs, HHS expects 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 proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. In HHS's view, while this final rule does not impose substantial direct requirement costs on state and local

governments, this regulation has federalism implications due to potential 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.

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 NAIC, 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, HHS complied with the requirements of E.O. 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. For states that elected previously to operate an Exchange, those states had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating 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 state. A user fee is assessed on issuers under all existing Exchange models, including State Exchanges where the user fee is assessed by the state, SBE-FPs, and the FFEs. HHS solicited comment on the proposed user fee rate of 2.75 percent of monthly premiums for issuers in FFEs and 2.25 percent of monthly premiums for issuers in SBE-FPs.

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 the Congress and the Comptroller for review. This final rule is a "major rule" as that term is

²²⁵ <https://www.sba.gov/document/support-table-size-standards>.

²²⁶ Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

defined in 5 U.S.C. 804(2), because it is likely to result in an annual effect on the economy of \$100 million or more.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 13, 2021.

List of Subjects

31 CFR Part 33

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Age discrimination, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 155

Administrative practice and procedure, Advertising, Age discrimination, Brokers, Civil rights, Citizenship and naturalization, Conflict of interests, Consumer protection, Grant programs—health, Grants administration, 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, Sex discrimination, State and local governments, Technical assistance, Taxes, Women, Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Age discrimination, Alaska, Brokers, Citizenship and naturalization, Civil rights, 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, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Prescription drugs, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, the Department of the Treasury amends 31 CFR part 33 as set forth below:

PART 33—WAIVERS FOR STATE INNOVATION

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

Authority: Sec. 1332, Pub. L. 111–148, 124 Stat. 119.

■ 2. Amend § 33.108 by revising paragraphs (f)(3)(iv) introductory text and (f)(3)(iv)(A) through (C) to read as follows:

§ 33.108 Application procedures.

* * * * *

(f) * * *

(3) * * *

(iv) The analyses, actuarial certifications, data, assumptions, targets, and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of Health and Human Services, as applicable, with the necessary data to determine that the State's proposed waiver satisfies the general requirements for approval under section 1332(b)(1) of the Affordable Care Act consistent with the provisions of this paragraph (f)(3)(iv):

(A) As required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), will provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that the State seeks to waive. To satisfy the comprehensive coverage requirement, the Secretary and the Secretary of Health and Human Services, as applicable, must determine that the coverage under the State plan is forecasted to be at least as comprehensive overall for residents of the State as coverage absent the waiver;

(B) As required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), will provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide. To satisfy the affordability requirement, the Secretary and the Secretary of Health and Human Services, as applicable, must determine that the coverage under the State plan is forecasted to be as affordable overall for

State residents as coverage absent the waiver;

(C) As required under section 1332(b)(1)(C) of the Affordable Care Act (the scope of coverage requirement), will provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide. To satisfy the scope of coverage requirement, the Secretary and the Secretary of the Health and Human Services, as applicable, must determine that the State plan will provide coverage to a comparable number of State residents under the waiver as would have coverage absent the waiver; and

* * * * *

■ 3. Amend § 33.118 by revising the section heading and paragraphs (a) and (b)(3) and adding paragraphs (b)(5) and (g) to read as follows:

§ 33.118 Modification from the normal public notice requirements during an emergent situation.

(a) The Secretary and the Secretary of Health and Human Services may modify, in part, the State public notice requirements under § 33.112(a)(1), (b), (c), and (d) and the Federal public notice procedures under § 33.116(b) to expedite a decision on a proposed section 1332 waiver request during an emergent situation, when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. These flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life.

(b) * * *

(3) The State must, as applicable, detail in its request for a modification from State-level notice procedures under paragraph (a) of this section the justification for the request as it relates to the emergent situation and the alternative public notice procedures it proposes to implement at the State level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the State's request for a modification.

* * * * *

(5) The State must explain in its request for a modification from State-level notice procedures under paragraph (a) of this section how the emergent circumstances underlying its request

results from a natural disaster; public health emergency; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life could not reasonably have been foreseen and how a delay would undermine or compromise the purpose of the waiver and be contrary to the interests of consumers.

* * * * *

(g) The Departments will consider circumstances to be emergent when they could not have been reasonably foreseen. The Departments will assess "reasonable foreseeability" based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and will not make this assessment based solely on the number of days a State may have been aware of such issues.

■ 4. Amend § 33.120 by revising paragraphs (a) and (c)(2)(i) and adding paragraphs (c)(2)(ii)(F) and (c)(2)(iii) to read as follows:

§ 33.120 Monitoring and compliance.

(a) *General.* (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of Health and Human Services, as applicable, a State must comply with all applicable Federal laws and regulations, unless expressly waived. A State must, within the timeframes specified in law and regulation come into compliance with any changes in Federal law and regulation affecting section 1332 waivers, unless the provision being changed is expressly waived.

(2) The Secretary and the Secretary of Health and Human Services will examine compliance with Federal and regulatory requirements consistent with § 155.1308(f)(3)(iv) when conducting implementation reviews under paragraph (b) of this section.

* * * * *

(c) * * *

(2) * * *

(i) The Secretary and the Secretary of Health and Human Services may modify, in part, State post award requirements under this paragraph (c)(2) for an approved section 1332 waiver request during an emergent situation, when the application of the post award public notice requirements would be contrary to the interests of consumers. These flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life.

(ii) * * *

(F) The State must explain in its request for modification under this paragraph (c)(2) how the emergent circumstances underlying its request results from a natural disaster; public health emergency; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life and could not reasonably have been foreseen and how the application of the post-award public notice requirements would be contrary to the interests of consumers.

(iii) The Secretary and the Secretary of Health and Human Services will consider circumstances to be emergent when they could not have been reasonably foreseen. The Secretary and the Secretary of Health and Human Services will assess "reasonable foreseeability" based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and will not make this assessment based solely on the number of days a State may have been aware of such issues.

* * * * *

■ 5. Section 33.122 is added to read as follows:

§ 33.122 Pass-through funding for approved waivers.

(a) *Pass-through funding.* With respect to a State's approved section 1332 waiver, under which, due to the structure of the approved State waiver plan, individuals and small employers in the State would not qualify for or would qualify for a reduced amount of premium tax credit under section 36B of the Internal Revenue Code, small business tax credit under section 45R of the Internal Revenue Code, or cost-sharing reductions under ACA part I of subtitle E for which they would otherwise be eligible, the Secretary and the Secretary of the Health and Human Services shall provide for an alternative means by which the aggregate amount of such credits or reductions that would have been paid on behalf of participants in the Exchanges had the State not received such waiver shall be paid to the State for purposes of implementing the approved State waiver plan. Such amount shall be determined annually by the Secretary and the Secretary of Health and Human Services, taking into consideration the experience of other States with respect to participation in an Exchange and credits and reductions provided under such provisions to residents of the other States. This amount can be updated to reflect

applicable changes in Federal or State law.

(b) [Reserved]

■ 6. Amend § 33.128 by revising paragraph (a) to read as follows:

§ 33.128 Periodic evaluation requirements.

(a) The Secretary and the Secretary of Health and Human Services, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with § 33.108(f)(3)(iv) and any terms and conditions governing the section 1332 waiver.

* * * * *

■ 7. Section 33.130 is added to read as follows:

§ 33.130 Waiver amendment.

(a) *Amendment to an approved section 1332 waiver.* A State may request an amendment to an approved section 1332 waiver from the Secretary and the Secretary of Health and Human Services. A section 1332 waiver amendment is considered a change to an approved section 1332 waiver plan that is not otherwise allowable under the terms and conditions of an approved waiver, a change that could impact any of the section 1332 statutory guardrails or a change to the program design for an approved waiver. A State is not authorized to implement any aspect of the proposed amendment without prior approval by the Secretary and the Secretary of Health and Human Services.

(b) [Reserved]

■ 8. Section 33.132 is added to read as follows:

§ 33.132 Waiver extension.

(a) *Extension.* A State may request continuation of an approved section 1332 waiver, and such request shall be deemed granted unless the Secretary and the Secretary of Health and Human Services, within 90 days after the date of submission of a complete waiver extension request to the Secretary and the Secretary of Health and Human Services, either denies such request in writing or informs the State in writing with respect to any additional information that is needed in order to make a final determination with respect to the request.

(b) [Reserved]

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B, as set forth below.

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL INSURANCE MARKETS

■ 9. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

■ 10. Amend § 147.104 by revising paragraphs (b)(2)(i)(E) and (F) and adding paragraph (b)(2)(i)(G) to read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(E) Section 155.420(d)(12) of this subchapter (concerning plan and benefit display errors);

(F) Section 155.420(d)(13) of this subchapter (concerning eligibility for insurance affordability programs or enrollment in the Exchange); and

(G) Section 155.420(d)(16) of this subchapter (concerning eligibility for advance payments of the premium tax credit and household income, as defined in 26 CFR 1.36B–1(e), that is expected to be no greater than 150 percent of the Federal poverty level).

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

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

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 12. Amend § 155.210 by revising paragraph (e)(9) to read as follows:

§ 155.210 Navigator program standards.

* * * * *

(e) * * *

(9) The Exchange may require or authorize Navigators to provide information and assistance with any of the following topics. In federally-facilitated Exchanges, FY 2021 Navigator grantees will be required to perform these duties beginning with the Navigator grant funding awarded in FY 2022 for the second 12-month budget period of the 36-month period of performance. Beginning with Navigator grants awarded in 2022, including non-competing continuation awards, Navigators are required to provide

information and assistance with all of the following topics:

(i) Understanding the process of filing Exchange eligibility appeals;

(ii) Understanding and applying for exemptions from the requirement to maintain minimum essential coverage granted through the Exchange;

(iii) The Exchange-related components of the premium tax credit reconciliation process, and understanding the availability of IRS resources on this process;

(iv) Understanding basic concepts and rights related to health coverage and how to use it; and

(v) Referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about the Exchange application and enrollment process, and premium tax credit reconciliations.

* * * * *

§ 155.221 [Amended]

■ 13. Amend § 155.221 by removing paragraph (j).

■ 14. Amend § 155.410 by—

■ a. Revising paragraph (e)(3);

■ b. Adding paragraph (e)(4);

■ c. Revising paragraph (f)(2) introductory text; and

■ d. Adding paragraph (f)(3).

The revisions and additions read as follows:

§ 155.410 Initial and annual open enrollment periods.

* * * * *

(e) * * *

(3) For the benefit years beginning on January 1, 2018 through January 1, 2021, the annual open enrollment period begins on November 1 and extends through December 15 of the calendar year preceding the benefit year.

(4) For the benefit years beginning on or after January 1, 2022—

(i) Subject to paragraph (e)(4)(ii) of this section, the annual open enrollment period begins on November 1 of the calendar year preceding the benefit year and extends through January 15 of the benefit year.

(ii) For State Exchanges not utilizing the Federal platform, for the benefit years beginning on or after January 1, 2022, an alternative annual open enrollment period end date may be adopted, provided the end date is no earlier than December 15 of the calendar year preceding the benefit year.

(f) * * *

(2) For the benefit years beginning on January 1, 2016 through January 1, 2021, the Exchange must ensure coverage is effective—

* * * * *

(3) For benefit years beginning on or after January 1, 2022, the Exchange must ensure that coverage is effective—

(i) Subject to paragraph (f)(3)(ii) of this section—

(A) January 1, for QHP selections received by the Exchange on or before December 15 of the calendar year preceding the benefit year.

(B) February 1, for QHP selections received by the Exchange from December 16 of the calendar year preceding the benefit year through January 15 of the benefit year.

(C) The first of the following month, for QHP selections received by the 15 of a month after January, if applicable under paragraph (e)(4)(ii) of this section.

(D) The first of the second following month, for plan selections received between the 16th and the end of a month, beginning January 16 of the benefit year, if applicable under paragraph (e)(4)(ii) of this section.

(ii) For State Exchanges not utilizing the Federal platform, for a QHP selection received by the Exchange during the open enrollment period for which effective dates specified in paragraph (f)(3)(i) of this section would apply, the Exchange may provide a coverage effective date that is earlier than specified in such paragraph.

* * * * *

■ 15. Amend § 155.420—

■ a. In paragraph (a)(4)(ii)(B), by removing the phrase “enrollment; or” and adding in its place “enrollment;”;

■ b. By revising paragraph (a)(4)(ii)(C);

■ c. By adding paragraph (a)(4)(ii)(D);

■ d. By revising paragraph (a)(4)(iii) introductory text; and

■ e. By adding paragraphs (b)(2)(vii), (d)(16), and (f).

The revision and additions read as follows:

§ 155.420 Special enrollment periods.

(a) * * *

(4) * * *

(ii) * * *

(C) No later than January 1, 2024, if an enrollee or his or her dependents become newly ineligible for advance payments of the premium tax credit in accordance with paragraph (d)(6)(i) or (ii) of this section, the Exchange must allow the enrollee and his or her dependents to change to a QHP of any metal level, if they elect to change their QHP enrollment; or

(D) If an enrollee or his or her enrolled dependents qualify for a special enrollment period in accordance with paragraph (d)(16) of this section, the Exchange must allow the enrollee and his or her enrolled dependents to change to any available silver-level QHP

if they elect to change their QHP enrollment. If a qualified individual or a dependent who is not an enrollee qualifies for a special enrollment period in accordance with paragraph (d)(16) of this section and has one or more household members who are enrollees, the Exchange must allow the enrollee to add the newly enrolling household member to his or her current QHP; or, to change to a silver-level QHP and add the newly enrolling household member to this silver-level QHP; or, to change to a silver level QHP and enroll the newly enrolling qualified individual or dependent in a separate QHP;

(iii) For the other triggering events specified in paragraph (d) of this section, except for paragraphs (d)(2)(i), (d)(4), and (d)(6)(i) and (ii) of this section for becoming newly eligible or ineligible for CSRs and paragraphs (d)(8), (9), (10), (12), (14), and (16) of this section:

* * * * *

(b) * * *

(2) * * *

(vii) If a qualified individual or enrollee, or the dependent of a qualified individual or enrollee, who is eligible for advance payments of the premium tax credit, and whose household income, as defined in 26 CFR 1.36B-1(e), is expected to be no greater than 150 percent of the Federal poverty level, enrolls in a QHP or changes from one QHP to another one time per month in accordance with paragraph (d)(16) of this section, the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the month following plan selection, at the option of the Exchange.

* * * * *

(d) * * *

(16) At the option of the Exchange, a qualified individual or enrollee, or the dependent of a qualified individual or enrollee, who is eligible for advance payments of the premium tax credit, and whose household income, as defined in 26 CFR 1.36B-1(e), is expected to be no greater than 150 percent of the Federal poverty level, may enroll in a QHP or change from one QHP to another one time per month during periods of time when the applicable taxpayer's applicable percentage for purposes of calculating the premium assistance amount, as defined in section 36B(b)(3)(A) of the Internal Revenue Code, is set at zero.

* * * * *

(f) For purposes of this section, references to eligibility for advance payments of the premium tax credit refer to being eligible for such advance

payments in an amount greater than zero dollars per month. References to ineligibility for advance payments of the premium tax credit refer to being ineligible for such payments or being eligible for such payments but being eligible for a maximum of zero dollars per month of such payments.

■ 16. Amend § 155.1308 by revising paragraphs (f)(3)(iv) introductory text and (f)(3)(iv)(A) through (C) to read as follows:

§ 155.1308 Application procedures.

* * * * *

(f) * * *

(3) * * *

(iv) The analyses, actuarial certifications, data, assumptions, targets, and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of the Treasury, as applicable, with the necessary data to determine that the State's proposed waiver satisfies the general requirements for approval under section 1332(b)(1) of the Affordable Care Act consistent with the provisions of this paragraph;

(A) As required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), will provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that the State seeks to waive. To satisfy the comprehensive coverage requirement, the Secretary and the Secretary of the Treasury, as applicable, must determine that the coverage under the State plan is forecasted to be at least as comprehensive overall for residents of the State as coverage absent the waiver;

(B) As required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), will provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide. To satisfy the affordability requirement, the Secretary and the Secretary of the Treasury, as applicable, must determine that the coverage under the State plan is forecasted to be at least as affordable overall for State residents as coverage absent the waiver;

(C) As required under section 1332(b)(1)(C) of the Affordable Care Act (the scope of coverage requirement), will provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide. To satisfy the scope of coverage requirement, the Secretary and the Secretary of the Treasury, as applicable, must determine that the State plan will provide coverage to a comparable number of State residents under the waiver as would have coverage absent the waiver; and

* * * * *

■ 17. Amend § 155.1318 by revising the section heading and paragraphs (a) and (b)(3) and adding paragraphs (b)(5) and (g) to read as follows:

§ 155.1318 Modification from the normal public notice requirements during an emergent situation.

(a) The Secretary and the Secretary of the Treasury may modify, in part, the State public notice requirements under § 155.1312(a)(1), (b), (c), and (d) and the Federal public notice procedures under § 155.1316(b) to expedite a decision on a proposed section 1332 waiver request during an emergent situation, when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. These flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life.

(b) * * *

(3) The State must, as applicable, detail in its request for a modification from State-level notice procedures under paragraph (a) of this section the justification for the request as it relates to the emergent situation and the alternative public notice procedures it proposes to implement at the State level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the State's request for a modification.

* * * * *

(5) The State must explain in its request for a modification from State-level notice procedures under paragraph (a) of this section how the emergent circumstances underlying its request result from a natural disaster; public health emergency; or other emergent

situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life could not reasonably have been foreseen and how a delay would undermine or compromise the purpose of the waiver and be contrary to the interests of consumers.

* * * * *

(g) The Secretary and the Secretary of the Treasury will consider circumstances to be emergent when they could not have been reasonably foreseen. The Secretary and the Secretary of the Treasury will assess "reasonable foreseeability" based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and will not make this assessment based solely on the number of days a State may have been aware of such issues.

■ 18. Amend § 155.1320 by—

- a. Revising paragraph (a);
- b. Revising the subject heading for paragraph (c)(2);
- c. Revising paragraph (c)(2)(i); and
- d. Adding paragraphs (c)(2)(ii)(F) and (c)(2)(iii).

The revisions and additions read as follows:

§ 155.1320 Monitoring and compliance.

(a) *General.* (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of the Treasury, as applicable, a State must comply with all applicable Federal laws and regulations, unless expressly waived. A State must, within the timeframes specified in law and regulation come into compliance with any changes in Federal law and regulation affecting section 1332 waivers, unless the provision being changed is expressly waived.

(2) The Secretary and the Secretary of the Treasury will examine compliance with Federal and regulatory requirements consistent with § 155.1308(f)(3)(iv) when conducting implementation reviews under paragraph (b) of this section.

* * * * *

(c) * * *

(2) *Modification from the normal post award requirements during an emergent situation.* (i) The Secretary and the Secretary of the Treasury may modify, in part, State post award requirements under this paragraph (c)(2) for an approved section 1332 waiver request during an emergent situation when the application of the post award public notice requirements would be contrary to the interests of consumers. These flexibilities are limited to emergent situations, including natural disasters;

public health emergencies; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life.

(ii) * * *

(F) The State must explain in its request for a modification under paragraph (c)(2) of this section how the emergent circumstances underlying its request results from a natural disaster; public health emergency; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life and could not reasonably have been foreseen and how the application of the post award public notice requirements would be contrary to the interests of consumers.

(iii) The Secretary and the Secretary of the Treasury will consider circumstances to be emergent when they could not have been reasonably foreseen. The Secretary and the Secretary of the Treasury will assess "reasonable foreseeability" based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and will not make this assessment based solely on the number of days a State may have been aware of such issues.

* * * * *

■ 19. Section 155.1322 is added to subpart N to read as follows:

§ 155.1322 Pass-through funding for approved waivers.

(a) *Pass-through funding.* With respect to a State's approved section 1332 waiver, under which, due to the structure of the approved State waiver plan, individuals and small employers in the State would not qualify for or would qualify for a reduced amount of premium tax credit under section 36B of the Internal Revenue Code, small business tax credit under section 45R of the Internal Revenue Code, or cost-sharing reductions under ACA part I of subtitle E for which they would otherwise be eligible, the Secretary and the Secretary of the Treasury shall provide for an alternative means by which the aggregate amount of such credits or reductions that would have been paid on behalf of participants in the Exchanges had the State not received such waiver shall be paid to the State for purposes of implementing the approved State waiver plan. Such amount shall be determined annually by the Secretary and the Secretary of the Treasury, taking into consideration the experience of other States with respect to participation in an Exchange and credits and reductions provided under such provisions to residents of the other

States. This amount can be updated to reflect applicable changes in Federal or State law.

(b) [Reserved]

■ 20. Amend § 155.1328 by revising paragraph (a) to read as follows:

§ 155.1328 Periodic evaluation requirements.

(a) The Secretary and the Secretary of the Treasury, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with § 155.1308(f)(3)(iv) and any terms and conditions governing the section 1332 waiver.

* * * * *

■ 21. Section 155.1330 is added to subpart N to read as follows:

§ 155.1330 Waiver amendment.

(a) *Amendment to an approved section 1332 waiver.* A State may request an amendment to an approved section 1332 waiver from the Secretary and the Secretary of the Treasury. A section 1332 waiver amendment is considered a change to a section 1332 waiver plan that is not otherwise allowable under the terms and conditions of an approved waiver, a change that could impact any of the section 1332 statutory guardrails or a change to the program design for an approved waiver. A State is not authorized to implement any aspect of the proposed amendment without prior approval by the Secretary and the Secretary of the Treasury.

(b) [Reserved]

■ 22. Section 155.1332 is added to subpart N to read as follows:

§ 155.1332 Waiver extension.

(a) *Extension.* A State may request continuation of an approved section 1332 waiver, and such request shall be deemed granted unless the Secretary and the Secretary of the Treasury, within 90 days after the date of submission of a complete waiver extension request to the Secretary and the Secretary of the Treasury, either denies such request in writing or informs the State in writing with respect to any additional information that is needed in order to make a final determination with respect to the request.

(b) [Reserved]

**PART 156—HEALTH INSURANCE
ISSUER STANDARDS UNDER THE
AFFORDABLE CARE ACT, INCLUDING
STANDARDS RELATED TO
EXCHANGES**

■ 23. The authority citation for part 156 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 24. Amend § 156.115 by revising paragraph (a)(3) to read as follows:

§ 156.115 Provision of EHB.

(a) * * *
(3) With respect to the mental health and substance use disorder services, including behavioral health treatment

services, required under § 156.110(a)(5), comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations.

* * * * *

■ 25. Amend § 156.280 by revising the section heading and paragraph (e)(2)(ii) to read as follows:

§ 156.280 Segregation of funds for abortion services.

* * * * *

(e) * * *
(2) * * *
(ii) An issuer will be considered to satisfy the obligation in paragraph (e)(2)(i) of this section if it sends the policy holder a single monthly invoice or bill that separately itemizes the

premium amount for coverage of abortion services described in paragraph (d)(1) of this section; sends the policy holder a separate monthly bill for these services; or sends the policy holder a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services, and specifies the charge.

* * * * *

Xavier Becerra,
Secretary, Department of Health and Human Services.

Mark J. Mazur,
Deputy Assistant Secretary (Tax Policy), Department of the Treasury.

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Part III

Department of Transportation

Federal Aviation Administration

14 CFR Part 33

Special Conditions: magniX USA, Inc., magni350 and magni650 Model
Engines; Electric Engine Airworthiness Standards; Final Rule

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 33**

[Docket No. FAA-2020-0894; Special Conditions No. 33-022-SC]

Special Conditions: magniX USA, Inc., magni350 and magni650 Model Engines; Electric Engine Airworthiness Standards

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the magniX USA, Inc., (magniX), magni350 and magni650 model engines, which operate using electrical technology installed on the aircraft for use as an aircraft engine. These engines have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards applicable to aircraft engines. This design feature is an electric motor, controller, and high-voltage systems as the primary source of propulsion for an aircraft. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Effective October 27, 2021.

FOR FURTHER INFORMATION CONTACT: Mark Bouyer, AIR-624, Propulsion and Energy, Technical Innovation Policy Branch, Aircraft Certification Service, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238-7755; mark.bouyer@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

On April 18, 2019,¹ magniX applied for a type certificate for its magni350 and magni650 model electric engines.² The FAA has not previously type certificated an engine that primarily uses electrical technology for propulsion of the aircraft. Electric propulsion technology is substantially

different from the technology used in previously certificated aircraft engines that operate using aviation fuel; therefore, these engines introduce new safety concerns that need to be addressed in the certification basis.

As noted in the Notice of Proposed Special Conditions, the FAA used technical criteria from ASTM F3338-18, *Standard Specification for Design of Electric Propulsion Units for General Aviation Aircraft*,³ along with engine information from magniX and other information, to develop these special conditions. These special conditions establish a level of safety that is equivalent to the level of safety required by title 14, Code of Federal Regulations (14 CFR) part 33.

Type Certification Basis

Under the provisions of 14 CFR 21.17(a)(1), generally, magniX must show that magni350 and magni650 model engines meet the applicable provisions of 14 CFR part 33 in effect on the date of application for a type certificate.

If the Administrator finds that the applicable airworthiness regulations (e.g., 14 CFR part 33) do not contain adequate or appropriate safety standards for the magni350 and magni650 model engines because of a novel or unusual design feature, special conditions may be prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other engine model that incorporates the same novel or unusual design feature, these special conditions would also apply to the other engine model under § 21.101. The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.17(a)(2).

Novel or Unusual Design Feature

The magni350 and magni650 model engines will incorporate the following novel or unusual design feature:

An electric motor, controller, and high-voltage systems is used as the primary source of propulsion for an aircraft.

Discussion

14 CFR Part 33 Developed for Aircraft Engines That Operate Using Aviation Fuel

Aircraft engines make use of an energy source to drive mechanical

systems that provide propulsion for the aircraft. The turbine and reciprocating aircraft engines certified under part 33 use aviation fuel as an energy source. The technology that the FAA anticipated in the development of 14 CFR part 33 converts oxygen and fuel to generate energy through an internal combustion system, which generates heat and mass flow of combustion products for turning shafts attached to propulsion devices such as propellers and ducted fans. Part 33 regulations set forth standards for these engines and mitigate potential hazards resulting from failures and malfunctions. The nature, progression, and severity of engine failures are tied closely to the technology that engine manufacturers use in designing and manufacturing aircraft engines. These technologies involve chemical, thermal, and mechanical systems. Therefore, the existing engine regulations in 14 CFR part 33 address certain chemical, thermal, and mechanically induced failures specific to air and fuel combustion systems operating with cyclically loaded high-speed, high-temperature, highly-stressed components.

magniX's Electric Engines Are Novel or Unusual

The FAA's current airworthiness standards for aircraft engines, 14 CFR part 33, date back to 1964.⁴ The FAA based these airworthiness standards on aircraft engines that operate using aviation fuel; such engines have mechanical systems that provide propulsion for aircraft. However, the magniX magni350 and magni650 model engines have a novel or unusual design feature which uses an electrical energy source instead of aviation fuel to drive the mechanical systems. The electric engine is exposed to chemical, thermal, and mechanical operating conditions that are unlike those observed in internal-combustion systems. Therefore, 14 CFR part 33 does not contain adequate safety standards for the magniX magni350 and magni650 model engines' novel or unusual design feature.

The two models of electric engine that have been proposed by magniX will use electrical power instead of air and fuel combustion to propel the aircraft. These electric engines will be designed, manufactured, and controlled differently than aircraft engines that operate using aviation fuel. They will be built with an electric motor, controller, and high-voltage systems that draw energy from electrical storage or

¹ The Notice of Proposed Special Conditions, published on November 19, 2020 (85 FR 73644), inaccurately indicated June 4, 2019, as magniX's type certificate application date.

² magniX submitted a comment which notified the FAA that the magniX engine model numbers were changed from magni250 and magni500 to magni350 and magni650, respectively. The model number change does not represent a change in the certification requirements of the engine.

³ <https://www.astm.org/DATABASE.CART/HISTORICAL/F3338-18.htm>.

⁴ 29 FR 7452.

generating systems. The magniX motor, in both models, is a device that converts electrical energy into mechanical energy by electric current flowing through wire coils in the motor, producing a magnetic field that interacts with magnets on the rotating shaft. The controller is a system that consists of two main functional elements: the motor controller and an electric power inverter to drive the motor.⁵ The high-voltage system is a combination of wires and connectors that couple the motor and the controller.

In addition, the technology required to produce these high-voltage and high-current electronic components introduces potential hazards that do not exist in aircraft engines that operate using aviation fuel. For example, high-voltage transmission lines, electromagnetic fields, magnetic materials, and high-speed electrical switches form the electric engine's physical properties. However, this technology also exposes the aircraft to potential failures that are not common to aircraft engines that operate using aviation fuel, which could adversely affect safety.

magniX's Electric Engines Require a Mix of 14 CFR Part 33 Standards and Special Conditions

Although magniX's proposed electric engines incorporate a novel or unusual design feature that the FAA did not envisage during the development of its existing 14 CFR part 33 airworthiness standards, these engines share some basic similarities, in configuration and function, to engines that use the combustion of fuel and air, and therefore they require similar provisions to prevent common hazards (e.g., fire, uncontained high-energy debris, and loss of thrust control). However, the primary failure concerns and the probability of exposure to common hazards are different for the electric engines. This probability creates a need to develop special conditions to ensure the engine's safety and reliability.

14 CFR part 33 does not fully address aircraft engines like magniX's, which use electrical technology as the primary means of propelling the aircraft. This necessitates the development of special conditions to provide adequate airworthiness standards for these aircraft engines.

The requirements in 14 CFR part 33, subparts B through G, apply to aircraft engines that operate using aviation fuel. Subpart B applies to reciprocating and turbine aircraft engines. Subparts C and

D apply to reciprocating aircraft engines. Subparts E through G apply to turbine aircraft engines. As such, subparts B through G do not adequately address aircraft engines that operate using electrical technology. This necessitates the development of special conditions to ensure a level of safety commensurate with these subparts, as those regulatory requirements do not contain adequate or appropriate safety standards for aircraft engines that primarily use electrical technology to propel the aircraft.

Discussion of Special Conditions and Comments

The FAA issued Notice of Proposed Special Conditions No. 33-19-01-SC (the Notice) for these proposed engines. This document was published in the **Federal Register** on November 19, 2020 (85 FR 73644). The FAA received comments from eleven organizations and two individuals.

The organizations that commented were Wisk Aero (Wisk), Rolls-Royce North America (Rolls-Royce), GE Aviation (GE), Ampaire Inc. (Ampaire), Textron Aviation (Textron), Associacao Das Industrias Aeroespaciais Do Brasil (AIAB), Safran Electrical & Power (Safran), Airbus Commercial Aircraft (Airbus), magniX USA, Inc. (magniX), Transport Canada Civil Aviation (TCCA), and European Union Aviation Safety Agency (EASA).

The following summarizes each special condition proposed by the FAA; the pertinent comments, and the FAA's response, including whether the FAA made any changes in these final special conditions.

Special Condition No. 1, Applicability

The FAA proposed that Special Condition no. 1 would require magniX to comply with 14 CFR part 33, except for those airworthiness standards specifically and explicitly applicable only to reciprocating and turbine aircraft engines.

Comment Summary: TCCA commented that proposed Special Condition no. 1 could be read in different ways regarding which sections of 14 CFR part 33 apply directly to electric engines and that applicants might disagree when assessing the appropriate airworthiness requirements for their engine designs. TCCA also suggested a manner in which to reformat this special condition.

FAA Response: These special conditions are not intended for all electric engine projects, only for the two models of engine proposed by magniX. Addressing the 14 CFR, part 33 applicability portion of the comment,

the requirements in part 33, subpart B, are applicable to reciprocating and turbine aircraft engines. Subparts C and D are applicable to reciprocating aircraft engines. Subparts E through G are applicable to turbine aircraft engines. As the magni350 and magni650 model engines are not reciprocating or turbine engines, subparts B through G of part 33 are not applicable to these engines unless these special conditions expressly require compliance, as set forth herein. The FAA did not change the special condition as a result of this comment.

Comment Summary: TCCA requested that Special Condition no. 1 include an additional requirement. TCCA asked that the FAA require the applicant to specify, within the engine installation manual, the electrical bonding for the installation of the engine and its control system. TCCA explained that proper bonding is required to protect the engine and the control system from the effects of lightning and electrostatic electricity, noting that 14 CFR 33.5(a) does not explicitly require electrical bonding instructions to be included in the engine installation manual.

FAA Response: Special Condition no. 10(e) addresses environmental limits for the magniX engines, which include electromagnetic interference, high-intensity radiated fields, and lightning. The assessments that verify environmental limits account for the effects of electrical bonding. A special condition for electrical bonding is not required to establish proper electrical bonding. Special Condition no. 1 mandates compliance with § 33.5(a), which addresses all physical and functional interfaces with the aircraft, including TCCA's recommendation to specify electrical bonding details in the engine installation instructions. The FAA made no changes to the special condition as a result of this comment.

Comment Summary: Wisk stated the inclusion of the high voltage and high current electrical system within the system covered by the engine OEM introduces aspects of 14 CFR 23.2525 that have not typically been addressed by engine OEMs before. Wisk added that consideration within the proposed SC for these aspects would ensure a safer product during the development, flight test, and service lifecycle. Wisk proposed the FAA consider applying § 23.2525(a) and (b), and possibly other relevant regulations to the components between the controller and motor in the engine system.

FAA Response: The requirements Wisk identifies in their comment apply to system power generation, storage, and distribution. These special conditions

⁵ Sometimes this entire system is referred to as an inverter. Throughout this document, the controller and inverter will be referred to as the controller.

apply only to the magniX engine designs, which do not include the power systems addressed in 14 CFR 23.2525. These power systems are normally approved as part of the airplane. Therefore, any other relevant part 23 airplane requirements would also be addressed during the airplane certification program. The FAA did not change this special condition as a result of this comment.

Comment Summary: Wisk acknowledged that the high voltage and current electrical system is analogous to the traditional fuel system. As such, omitting regulations that are equivalent to all, or parts of 14 CFR 33.67 from these special conditions may result in a loss of a critical interface boundary, resulting in a lack of clear ownership between the airframe and engine OEM. Wisk requested that the FAA clarify within the proposed SC the analogous aspects of § 33.67 for the interface between the engine controller and the airframe electrical system as it relates to voltage and current.

FAA Response: 14 CFR 33.67 includes requirements for features that do not exist in the magniX engine electrical system. However, the analogous aspects of § 33.67 are included Special Condition no. 2, which requires magniX to establish and declare ratings and operating limits based on power-supply requirements for the engine. Therefore, Special Condition no. 2 addresses Wisk's comment. The FAA did not change this special condition as a result of this comment.

Special Condition No. 2, Engine Ratings and Operating Limits

The FAA proposed that Special Condition no. 2 would require magniX, in addition to compliance with 14 CFR 33.7(a), to establish engine operating limits related to the shaft horsepower, torque, speed, and duty cycle(s). The duty cycle is an engine rating that declares a performance capability for the load(s) that will be imposed on the engine, including, if applicable, starting, no-load and rest, and de-energized periods, including their durations or cycles and sequence in time.

Comment Summary: Wisk recommended that the FAA expand the ratings and operating limits required by Special Condition no. 2 to include maximum temperature, maximum and minimum voltage, current, and power; and, if applicable, coolant and/or lubrication temperatures & pressures for safe operation.

FAA Response: It is not necessary to impose voltage and current limits to ensure that these magniX engines achieve the same level of safety

intended by 14 CFR part 33. The FAA has changed final Special Condition no. 2 to add temperature and power (power-supply) requirements to the engine ratings and operating limits.

Comment Summary: Wisk stated that proposed Special Condition no. 2(a)(1) (Rated Maximum Continuous Power) should not have a time limit as it is continuous. Wisk suggested deleting the word "time" from proposed Special Condition no. 2(a).

FAA Response: The FAA agrees that the power at the "Rated Maximum Continuous Power" rating is not time limited. The FAA has modified final Special Condition no. 2 to remove the time constraint from the rating.

Comment Summary: Wisk suggested that the FAA specify coolant and lubrication temperatures and pressures for safe operation.

FAA Response: The FAA does not agree with Wisk's suggestion. A special condition is not required for coolant and lubrication (operating) temperatures. Special Condition nos. 6 (Engine cooling) and 14 (Lubrication system) address Wisk's suggestion. No changes were made to this special condition as a result of Wisk's comment.

Comment Summary: Rolls-Royce commented that, by placing a duty cycle on the engine's type certificate data sheet, proposed Special Condition no. 2 would be overly prescriptive when compared to the FAA's requirements for aircraft engines that operate using aviation fuel. Rolls-Royce stated that Special Condition no. 2(b) should be removed, and the FAA should require the applicant to define a duty cycle in the Airworthiness Limitations Section of the Operating Manual.

FAA Response: The magni350 and magni650 electric engines have different operating characteristics than conventional reciprocating or turbine engines. The performance capability of electric engine designs is defined, in part, by a duty cycle. Therefore the FAA did not change this special condition as a result of this comment.

Comment Summary: GE recommended that the FAA modify Special Condition no. 2 to require the applicant to list the engine's cooling fluid as an engine operating limitation, similar to 14 CFR 33.7(b)(3), which requires, for reciprocating engines, established ratings and operating limitations related to oil grade or specification.

FAA Response: The FAA agrees with the comment and has modified final Special Condition no. 2 to require a cooling fluid grade or specification as an operating limit.

Comment Summary: Ampaire commented that the term "power," as used in proposed Special Condition no. 2, is not the most relevant metric for electric machinery and power electronics. Ampaire stated that it understood "power," as used in that condition, to be the electrical power output delivered by the magniX engine. Ampaire recommended that the FAA change the requirement to specify current and voltage.

FAA Response: The FAA does not agree with the comment. As used in Special Condition no. 2, "power" describes the mechanical shaft horsepower supplied by the engine to propel the aircraft and not the electrical power delivered by the engine. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: Ampaire asked that the FAA include more details from ASTM F3338–18, such as those listed in sections 5.3.1–5.3.8, EPU Operating Limitations and Ratings, in Special Condition no. 2.

FAA Response: The FAA does not agree with the comment. ASTM F3338–18 contains technical criteria that the FAA used in developing these special conditions. The airworthiness requirements for these engines include paragraphs from the ASTM specification and from 14 CFR part 33. The FAA made no changes to the special condition as a result of this comment.

Comment Summary: Textron recommended that the FAA add engine temperature to the ratings and operating limits mandated by Special Condition no. 2.

FAA Response: The FAA agrees with the comment. The FAA has changed final Special Condition no. 2 to add temperature to the engine ratings and operating limits.

Comment Summary: Textron stated the term "speed," as used in Special Condition no. 2(a), could be misleading and mistaken for aircraft speed or gearbox output-shaft speed. Textron stated the term "speed" should instead be "RPM."

FAA Response: The FAA does not agree with the comment. Engine speed is typically measured in units that describe a rate of mechanical rotation. In Special Condition no. 2, the word "speed," used in the context of "rotational speed," applies to the output-shaft rotation rate. The applicant can express engine speed using various units, so the measurement unit of the engine shaft rotation does not need to be prescribed in Special Condition no. 2. The FAA did not change the special condition based on the comment.

Comment Summary: Textron recommended that the FAA add rated takeoff power to the required engine ratings and operating limits in Special Condition no. 2.

FAA Response: The FAA agrees and has added “rated takeoff power” to the engine ratings and operating limits in final Special Condition no. 2.

Comment Summary: TCCA suggested that the engine ratings and operating limits not be limited to those proposed in Special Condition no. 2(a). TCCA recommended adding a statement that requires magniX to include any other ratings or limitations that are necessary for the safe operation of the engine.

FAA Response: The engine ratings and operating limits that Special Condition no. 2 requires are based on existing aircraft engine technologies. However, electric engine technology is new to aviation. The FAA has modified Special Condition no. 2 to require additional ratings if they are determined to be necessary for the safe operation of the engine.

Comment Summary: TCCA asked why the FAA did not mandate that the applicant comply with 14 CFR 33.7(d) within Special Condition no. 2. Similarly, AIAB commented that Special Condition no. 2 should mandate compliance with 14 CFR 33.7(d), since the electric motor can be affected by the accuracy of the engine control system and instrumentation.

FAA Response: The FAA does not agree with the comment. Special Condition no. 1 requires that the proposed design complies with §§ 33.7(a), 33.7(d), as those requirements are not expressly and explicitly applicable only to reciprocating and turbine engines. The FAA did not change Special Condition no. 2 as a result of these comments.

Comment Summary: TCCA stated that Special Condition no. 2, as proposed, provided requirements “in addition to § 33.7(a),” and then proceeds to replace all of the § 33.7 details with Special Condition no. 2 requirements. TCCA stated the replacement of § 33.7 with Special Condition no. 2, as proposed, removes the determination by the FAA, as well as the concept of “any other information found necessary for the safe operation of the engine.” TCCA indicated that § 33.7, combined with § 33.8, should be referenced in the special condition to provide the essential cornerstone for establishing aircraft performance based on installed rated power.

FAA Response: The FAA does not agree with the comment. Special Condition no. 1 requires that the proposed design complies with

§§ 33.7(a), 33.7(d), and 33.8. Special Condition no. 2 provides requirements in addition to those in § 33.7(a). The concern stated by TCCA is remedied by the inclusion of §§ 33.7(a), 33.7(d), and 33.8 within Special Condition no. 1. No change was made to this special condition as a result of the comment.

Comment Summary: Regarding the reference to “duty cycle” in proposed Special Condition no. 2(b), and the rating (singular) at that duty cycle, TCCA recommended that the FAA clarify whether the duty cycle corresponds to a flight cycle, a series of flights, or an engine test cycle.

FAA Response: The term duty cycle in Special Condition no. 2 is an engine rating that declares a performance capability for the load(s) that will be imposed on the magniX engines. These capabilities are determined by tests that may include starting, no-load and rest, de-energized periods and their durations (or cycles), and sequence. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: TCCA commented that proposed Special Condition no. 2 omitted consideration of electric engines’ capability to regenerate electrical power. TCCA recommended that the special conditions provide design, construction, and testing that demonstrate this new capability, while acknowledging that this issue is partially addressed by Special Condition no. 31 (Operation with a variable pitch propeller).

FAA Response: Although electric engines are capable of regenerating electrical power, these special conditions apply only to the magniX engine designs, which are not intended to provide electrical power to an aircraft. Therefore the FAA did not change these special conditions as a result of this comment.

Comment Summary: TCCA suggested that the Special Condition no. 10 should be modified to include the following: “If any electrical power is supplied from the aircraft to the engine control system for powering on and operating the engine, the need for and the characteristics of this electrical power, including transient and steady-state voltage limits, must be identified and declared in the engine installation manual.”

FAA Response: The FAA modified Special Condition no. 2 as a result of Wisk’s comment and TCCA’s comment for Special Condition no. 10. The change requires the applicant to establish ratings and operating limits for power-supply requirements, which include voltage and current, to be

included in the type certificate data sheet.

Comment Summary: TCCA stated that Special Condition nos. 2(a)(1) and 2(a)(2) address power and time limits and asked if the limits are based on an expected power supply and whether the power supply will be part of the baseline configuration. TCCA recommended including another special condition explaining how the power-supply characteristics will be addressed in the declaration of power ratings and operational limits.

FAA Response: The term “power,” as used in Special Condition nos. 2(a)(1) and 2(a)(2), refers to engine shaft horsepower. Special Condition no. 2 has been modified to include the terms “shaft power” and “rated takeoff power.”

Comment Summary: TCCA suggested that the FAA modify Special Condition no. 2 to require the propeller overspeed limit to be defined in the engine installation manual for situations involving propeller control malfunctions. TCCA recommended that the FAA add a special condition that requires a “get-home” capability.

FAA Response: The FAA does not agree with the comment. The propeller has its own type certificate, documented ratings, and operating limits, including an overspeed limit. These engines will also have their own ratings and operating limits, including an overspeed limit. Propeller overspeed protection will be managed using the engine and propeller installation manuals’ declared ratings and operating limits. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: TCCA recommended incorporating the following text to the special conditions: “Each selected rating must be for the lowest power that all engines of the same type may produce under the conditions used to determine that rating at all times between overhaul periods or other maintenance.”

FAA Response: Special Condition no. 1 includes a requirement for magniX to comply with 14 CFR 33.8, so the existing requirement in part 33 is applicable to these engines. Special Condition no. 29 (Teardown inspection) requires the engine to be within service limits and eligible for continued operation in accordance with the information submitted for showing compliance with § 33.4, *Instructions for Continued Airworthiness*. Therefore, these special conditions address the recommendation by TCCA. The FAA made no changes to the special condition as a result of the comment.

Special Condition No. 3, Materials

The FAA proposed that Special Condition no. 3 would require the design of these engines to comply with 14 CFR 33.15, which sets requirements for the suitability and durability of materials used in the engine, and which would otherwise be applicable only to reciprocating and turbine aircraft engines.

Comment Summary: Textron highlighted the potential hazards from certain electronic components, such as aging electrolytic capacitors. Textron recommended that the FAA require periodic testing of electrolytic capacitors to determine an appropriate replacement interval to avoid hazardous effects at altitude such as breakdown, corona, flashover, creep, strike distance, and cooling.

FAA Response: These special conditions address the hazards that may result from failure or malfunction of electronic components. Special Condition no. 27 (System and component tests) is a performance-based requirement in which the applicant must show that systems and components will perform their intended functions in all declared environmental and operating conditions. This requirement addresses all types of component failures, including those referenced in Textron's comment. Special Condition no. 13 (Critical and life-limited parts) requires the applicant to show, by a safety analysis or means acceptable to the Administrator, whether rotating or moving components, bearings, shafts, static parts, and non-redundant mount components should be classified, designed, manufactured, and managed throughout their service life as critical or life-limited parts, including electronic parts and components. Special Condition no. 10(g) (Engine control systems) requires the applicant to conduct a control system safety assessment to identify the hazards resulting from control system failures and malfunctions, such as those in Textron's comment. The FAA made no changes to these special conditions as a result of this comment.

Comment Summary: TCCA recommended that these special conditions address the potential for manufacturing errors by appending the following text: "In addition, manufacturing methods and processes must be such as to produce sound structure and mechanisms, and electrical systems that retain the design properties under assumed service conditions declared in the engine installation manual. This includes the

effects of deterioration over time, e.g., corrosion."

FAA Response: The 14 CFR part 33 airworthiness requirement for materials (§ 33.15) applies to these engines. The existing part 33 materials requirement is adequate and appropriate for the certification basis for these engines. The FAA made no changes to the special condition as a result of the comment.

Special Condition No. 4, Fire Protection

The FAA proposed that Special Condition no. 4 would require the design of these engines to comply with 14 CFR 33.17, which sets requirements to protect the engine and certain parts and components of the airplane against fire, and which would otherwise be applicable only to reciprocating and turbine aircraft engines. Additionally, this special condition proposed to require magniX to ensure the high-voltage electrical wiring interconnect systems that connect the controller to the motor are protected against arc faults. An arc fault is a high power discharge of electricity between two or more conductors. This discharge generates heat, which can break down the wire's insulation and trigger an electrical fire. Arc faults can range in power from a few amps to thousands of amps and are highly variable in strength and duration.

Comment Summary: GE proposed that the special conditions include a provision for non-protected electrical wiring interconnects that requires the applicant to conduct an analysis to show that arc faults do not cause hazardous engine effects. GE stated that if electrical wiring interfaces with aircraft parts or components, the potential for arc faults should be communicated to the aircraft manufacturer. In addition, GE recommended that the FAA require the applicant to declare potential arc faults in the engine installation manual.

FAA Response: This special condition has provisions to prevent arc faults in high-voltage wire interconnecting systems from causing hazardous engine effects. Additionally, Special Condition no. 17 (Safety analysis) will have the effect of requiring magniX to account for the intended aircraft application in the engine installation manual. 14 CFR 33.5(c), "*Instruction manual for installing and operating the engine,*" applies to the two magniX engines. These requirements will generate the recommended documentation, such as installation instructions. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: TCCA stated that no special conditions provide standards

for the electrical connectors supplied with the motor. TCCA requested clarification of the FAA's intent.

FAA Response: The special condition is a performance-based requirement, which allows flexibility for magniX to design and substantiate components (such as connectors) that they use in their engine design. The FAA made no changes to the special condition as a result of the comment.

Special Condition No. 5, Durability

The FAA proposed that Special Condition no. 5 would require the engine design and construction to ensure safe engine operation between maintenance intervals, overhaul periods, and mandatory actions described in the applicable ICA.

Comment Summary: Textron noted that the proposed wording of Special Condition no. 5 matched the intent of 14 CFR 33.19(a) but omitted the requirements of § 33.19(b). Textron suggested that Special Condition no. 5 include the following: "Each component of the propeller-blade pitch control system which is part of the engine type design must meet the requirements of §§ 35.21, 35.23, 35.42 and 35.43."

TCCA provided a similar comment, asking why § 33.19(b) was omitted and seeking its inclusion in Special Condition no. 5.

FAA Response: These special conditions apply only to the two magniX engine designs, which do not include a propeller-blade pitch control system. The FAA made no changes to the special condition as a result of the comments.

Comment Summary: TCCA recommended that the FAA include the requirements from 14 CFR 33.5(b) into these special conditions, as the controller may include propeller control functions.

FAA Response: These special conditions apply only to the proposed magniX engine designs, which do not include propeller controls and controllers. In addition, Special Condition no. 1 mandates compliance with § 33.5(b), "*Instruction manual for installing and operating the engine,*" which addresses this comment. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: TCCA stated the requirements from 14 CFR 33.4 are missing from these special conditions, but noted that including all instructions for off-wing maintenance that were contained in the ICA, would not be appropriate.

FAA Response: These special conditions are not intended for all electric engine certification projects. As

provided in Special Condition no. 1, § 33.4, *Instructions for continued airworthiness*, and its appendix, apply to the magniX engines. The FAA made no changes to the special condition as a result of the comment.

Special Condition No. 6, Engine Cooling

The FAA proposed that Special Condition no. 6 would require the engine design and construction to comply with 14 CFR 33.21. That regulation requires the engine design and construction to provide necessary cooling under conditions in which the airplane is expected to operate and would otherwise be applicable only to reciprocating and turbine aircraft engines. Additionally, this special condition proposed to require the applicant to document the cooling system monitoring features and usage in the engine installation manual, if cooling is required to satisfy the safety analysis described in Special Condition no. 17. Loss of adequate cooling to an engine that operates using electrical technology can result in rapid overheating and abrupt engine failure with critical consequences to safety.

Comment Summary: GE suggested that Special Condition no. 6 is redundant to Special Condition no. 17 (Safety analysis) because it includes 14 CFR 33.75(d) *Safety analysis*, and should be deleted.

FAA Response: The FAA does not agree with the suggested change. The reference to § 33.75(d) in Special Condition no. 17 does not explicitly address cooling systems that are necessary for the engine to comply with the safety analysis. Special Condition no. 6 requires additional information about the cooling system that is not specified in § 33.75(d). The FAA made no change to Special Condition no. 6 as a result of this comment.

Comment Summary: Ampaire suggested that, given certain assumptions, the electric engine manufacturer may need to specify cooling limits that cannot be exceeded at the aircraft and engine interface to ensure safe operation.

FAA Response: The FAA does not agree with the comment. These special conditions are applicable only to the magniX magni350 and magni650 model engines. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: Rolls-Royce stated that the cooling system monitoring and documentation requirements in proposed Special Condition no. 6 are already covered in 14 CFR 33.29(h), “Instrument connection.” Rolls-Royce recommended

that the FAA modify § 33.29(h) to include a statement of applicability to electric engines.

TCCA recommended adding, “The cooling system monitoring must be made available to enable the flight crew or the automatic control system to monitor the functioning of the engine cooling system.”

FAA Response: The FAA does not agree to amend 14 CFR 33.29(h) as a result of Rolls-Royce’s comment, as these special conditions are of particular applicability to the magni350 and magni650 model engines only. However, as a result of Rolls-Royce’s and TCCA’s comments that recommend applying cooling system monitoring to the magniX engines, the FAA has added paragraph (b) to final Special Condition no. 11 to incorporate the requirements of 14 CFR 33.29(h), except for those provisions specifically applicable to turbine aircraft engines.

Comment Summary: TCCA recommended adding, “If aspects of the engine cooling system require the installer to ensure that the temperature limits are met, those limits must be specified in the installation manual.”

FAA Response: The FAA does not agree with TCCA’s comment. Special Condition no. 24 requires magniX to establish a temperature limit. If the temperature limit is necessary for the safe operation of the engine, these special conditions require the limit to be documented in the installation manual. Therefore, a special condition is not needed to mandate information specified in TCCA’s comment.

Comment Summary: TCCA recommended adding, “Any reliance placed upon the assumed installed conditions, or installation requirements must be declared in the instructions for installation.”

FAA Response: The FAA does not agree with TCCA’s comment. Special Condition no. 1 requires magniX to comply with 14 CFR 33.5. Therefore, these special conditions already require the information specified in TCCA’s comment to be documented in the instructions for installing the engine.

Comment Summary: TCCA recommended adding “magniX must prepare and make available to the Agency prior to the issuance of the type certificate, and to the installer at the time of delivery of the engine, approved instructions for installing and operating the engine.”

FAA Response: The FAA does not agree with TCCA’s comment. Special Condition no. 1 requires magniX to comply with 14 CFR 33.4, which requires magniX to prepare Instructions for Continued Airworthiness in

accordance with appendix A to that part. Appendix A requires the Instructions for Continued Airworthiness include instructions for installing and operating the engine. Special Condition no. 1 also mandates compliance with 14 CFR 33.5, which requires magniX to prepare and make available to the Administrator, prior to the issuance of the type certificate, and to the owner at the time of delivery of the engine, approved instructions for installing and operating the engine. The FAA made no changes to the special condition as a result of the comment.

Special Condition No. 7, Engine Mounting Attachments and Structure

The FAA proposed that Special Condition no. 7 would require these engines to comply with 14 CFR 33.23, which requires the applicant to define the proposed design to withstand certain load limits for the engine mounting attachments and related engine structure. These requirements would otherwise be applicable only to reciprocating and turbine aircraft engines.

Comment Summary: Textron stated that a propeller could be a much higher percentage of the total propulsion system mass in electric systems than for reciprocating or turbine engine propulsion systems and suggested that an electric motor’s rotating components can be nearly instantly coupled to the non-rotating components due to FOD, internal failure, rotor growth, and commutation errors. Textron proposed additional requirements to Special Condition no. 7 related to sudden stoppage and bearing protection to ensure the engine mounting system can absorb the load or mitigate the effect of the load on aircraft.

FAA Response: The FAA does not agree with the comment. The certification basis for the proposed engines includes 14 CFR 33.23, *Engine mounting attachments and structure*, which is a performance-based requirement. The regulation doesn’t specify how maximum and ultimate loads are determined because these load conditions are determined by magniX. Also, Special Condition no. 2 requires magniX to establish a torque limit and Special Condition no. 21 requires magniX to establish a maximum overtorque limit. These requirements address the conditions described in Textron’s comment. magniX’s engines must be designed to accommodate the load at these limit values. These special conditions address high engine mount load conditions, including the conditions described in Textron’s comment, except for loads from the

failure considerations that are normally addressed by Special Condition no. 17 (Safety Analysis). The FAA made no changes to the special condition as a result of the comment.

Comment Summary: Textron recommended adding a requirement for bearing protection that states, “Engine bearings must be protected from rotor voltage or a periodic replacement interval shall be determined as defined in Special Condition no. 13.”

FAA Response: The FAA agrees with the technical content of this comment, but there is no requirement in these special conditions to add rotor shaft grounding technology in the magniX engines. Bearings could experience accelerated wear-out from ungrounded shafts, but the failure should not present a safety issue because the failure is predictable with sufficient testing. Requirements such as § 33.4, *Instructions for Continued Airworthiness*, Special Condition no. 3 (Materials), Special Condition no. 5 (Durability), Special Condition no. 13 (Critical and life-limited parts), and Special Condition no. 29 (Teardown inspection) will all have a role in managing the consequences of potential bearing wear from electrical effects. magniX may assess the impact to product support at the predicted bearing replacement frequency and decide to include rotor shaft grounding technology.

Comment Summary: TCCA recommended that the FAA add a requirement to this special condition, requiring the applicant to demonstrate that the engine mounts and mounting features are fireproof if flammable fluids are used within the engine.

FAA Response: The FAA does not agree with the comment. The fire protection requirements in 14 CFR 33.17 apply to the magniX engines. The FAA made no changes to the special condition as a result of the comment.

Special Condition No. 8, Accessory Attachments

The FAA received no comments for Special Condition no. 8, and it is adopted as proposed. It requires the engine to comply with 14 CFR 33.25, which sets certain design, operational, and maintenance requirements for the engine’s accessory drive and mounting attachments, and which would otherwise be applicable only to reciprocating and turbine aircraft engines.

Special Condition No. 9, Overspeed

The FAA proposed that Special Condition no. 9 would require magniX to establish by test, validated analysis,

or a combination of both, that: (1) The rotor overspeed not result in a burst, rotor growth, or damage that results in a hazardous engine effect; (2) rotors possess sufficient strength margin to prevent burst; and (3) operating limits of the engine not be exceeded in-service.

Comment Summary: GE stated that proposed Special Condition no. 9(c) was duplicative of Special Condition no. 10(b) and (h) (Engine control systems), and requested the special condition be removed.

FAA Response: The FAA does not agree with the comment. The special conditions referenced by GE accomplish different safety objectives. Special Condition no. 9(c) requires that the engine must not exceed the rotor speed operational limitations that could affect rotor structural integrity. This requirement results in an overspeed limit. Special Condition no. 10(b) requires the engine control system must ensure the engine does not experience any unacceptable operating characteristics or exceed its operating limits, including in failure conditions where the fault or failure results in a change from one control mode to another, from one channel to another, or from the primary system to the back-up system, if applicable. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: Ampaire stated that Special Condition no. 9 (Overspeed) should include more information from ASTM F3338–18.

FAA Response: The FAA does not agree with the comment. ASTM F3338–18 section 5.9, EPU Rotor Overspeed, contains technical criteria that the FAA used in developing these special conditions. It also contains information that the applicant can use to propose means of compliance to these special conditions. The FAA did not change this special condition as a result of this comment.

Comment Summary: Textron recommended that the FAA modify Special Condition no. 9, paragraphs (a) and (c), replacing “speed” with “RPM.” Textron reasoned that the term “speed” could be misleading.

FAA Response: The units used for rotational speed in the limitations section of the engine manual can be expressed using various units. The FAA recognizes that “rpm” is used in 14 CFR 33.88, *Engine overtemperature test* and § 33.201, *Design and test requirements for Early ETOPS eligibility*, but speed units are not specified in all regulations that mention engine rotor speed. Therefore, the FAA will maintain the term “speed” in these special conditions. The FAA did not change

this special condition as a result of this comment.

Comment Summary: TCCA stated that proposed Special Condition no. 9 suggested that the controller will provide the engine overspeed protection and commented that the FAA should ensure that the overspeed protection will function as intended when exposed to high-intensity radiated fields (HIRF), lightning environments, and threats. TCCA stated that verification of this protection might require the electric motor and engine control system to be included in the test setup when conducting the HIRF and lightning transient system tests and recommended that these special conditions clarify this topic in the discussion section of these special conditions.

FAA Response: This special condition is a performance-based requirement, and test details will be established as part of the demonstration of compliance. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: TCCA recommended that the FAA modify “Rotors must possess” as stated in Special Condition no. 9(b), to “Rotors, including any integral fan rotors used for cooling, must possess.”

FAA Response: These special conditions are not generally applicable to all electric engines; they apply only to the applicant’s proposed engines. The magniX engines do not use integral fan rotors to cool the engine. The FAA did not change this special condition as a result of the comment.

Special Condition No. 10, Engine Control Systems

The FAA proposed that Special Condition no. 10 would impose several requirements.

Special Condition no. 10(a) proposed that the requirements of that special condition apply to any engine system or device that controls, limits, monitors, or protects engine operation and is necessary for the continued airworthiness of the engine.

Special Condition no. 10(b) proposed to require that an engine control system ensure that the engine does not experience any unacceptable operating characteristics (such as unstable speed or torque control) or exceed any of its operating limits.

Special Condition no. 10(c) proposed to require magniX to systematically design, develop, and verify the software and complex electronic hardware, including programmable logic devices. RTCA DO-254, *Design Assurance Guidance for Airborne Electronic*

Hardware, dated April 19, 2000,⁶ distinguishes between complex and simple electronic hardware.

Special Condition no. 10(d) proposed to require the applicant to substantiate all functional aspects of the control system to show that it performs its intended functions throughout the declared operational envelope.

Special Condition no. 10(e) proposed to require the system and component tests in Special Condition no. 27 to demonstrate the control will function as intended at environmental limits that magniX cannot otherwise substantiate. These limits include temperature, vibration, HIRF, and other limits addressed in RTCA DO-160G, *Environmental Conditions and Test Procedures for Airborne Electronic/Electrical Equipment and Instruments*⁷ (DO-160G) or other appropriate industry standards for airborne environmental-conditions testing, such as Mil-STD-810 “Environmental Engineering Considerations and Laboratory Tests,” Mil-STD-202 “Test Method Standard for Electronic and Electrical Component Parts,” Mil-461 “Requirements for the Control of Electromagnetic Interference Characteristics of Subsystems and Equipment,” and those listed in Advisory Circular 21-16G, RTCA Document DO-160 versions D, E, F, and G, “Environmental Conditions and Test Procedures for Airborne Equipment,” Special Condition no. 10(e) also requires magniX to document the environmental limits to which the system has been qualified in the engine installation manual.

Special Condition no. 10(f) proposed to require the engine control system not to exceed a maximum rate of Loss of Power Control (LOPC) for the aircraft types that will use the magniX engines, be single-fault tolerant in the full-up configuration, not have any single failure that results in hazardous engine effects, and not have any likely failure or malfunction that lead to local events in the intended installation.

The FAA issued Advisory Circular AC 33.28-3, *Guidance Material For 14 CFR 33.28, Engine Control Systems*, on May 23, 2014.⁸ Paragraph 6-2 of this AC provides applicants with guidance about defining an engine control system failure when showing compliance with the requirements of § 33.28. It also explains the safety objectives of the requirements, provides criteria for a loss

of thrust control (LOTC)/LOPC events for reciprocating and turbine engines. However, the guidance in AC 33.28-3 may not have sufficient information to identify failure modes and establish acceptable LOTC/LOPC rates for the magniX electric engines because electric engines did not exist when the FAA issued this AC.

The phrase “in the full-up configuration” used in Special Condition no. 10(f)(2) refers to a system without any fault conditions present. When in the full-up configuration, the electronic control system must be single fault tolerant for electrical, electrically detectable, and electronic failures involving LOPC events.

The term “local events” used in Special Condition no. 10(f)(4) means failures or malfunctions that could lead to hazardous effects such as fire, overheat, or failures causing damage to engine control system components.

Special Condition no. 10(g) proposed to require magniX to conduct a system safety assessment to support the safety analysis in Special Condition no. 17.

Special Condition no. 10(h) proposed to require that the design and function of the engine control devices and systems, together with the engine instruments, operating instructions, and maintenance instructions, ensure that engine operating limits will not be exceeded in-service.

Special Condition no. 10(i) proposed to protect the airplane and engine from single failures relating to the aircraft-supplied data by mandating that the control system is able to detect and accommodate such failures, and not result in a hazardous engine effect.

The term “independent,” as it is used in “fully independent engine systems,” means that the controllers should be either self-sufficient and isolated from other aircraft systems or provide redundancy. In the case of loss, interruption, or corruption of aircraft-supplied data, the engine must continue to function without hazardous engine effects.

The term “accommodated” means that when a fault has been detected, the system must continue to function safely.

Special Condition no. 10(j) proposed to require magniX to show that the loss, malfunction, or interruption of the control system electrical power source will not result in a hazardous engine effect, the unacceptable transmission of erroneous data, or continued engine operation in the absence of the control function.

Comment Summary: Rolls-Royce asked that the FAA clarify the requirements contained in Special Condition nos. 10(f)(1) and (f)(2). The

commenter expressed concern that the single fault tolerance requirement in Special Condition no. 10(f)(2) would be applied to both historical electrical elements of the engine control system and to the new high-voltage electrical/electronic elements required to motivate an electric motor. Rolls-Royce commented that it was possible the wording of this condition would be extended to cover loss of power (LOP) events due to the difficulties of establishing the boundary between the control and the motor drive in an electric engine. Rolls-Royce asked the FAA to modify this special condition to clarify that the degree of fault tolerance in the high-voltage electrical/electronic elements will be governed by the LOP reliability requirement of Special Condition no. 10(f)(1), and not the single fault tolerance requirement of LOPC of Special Condition no. 10(f)(2). AIAB articulated a similar concern and recommended the FAA delete Special Condition no. 10(f)(2) in these final special conditions. AIAB stated a loss of thrust control (LOTC)/LOPC event could be considered minor in aircraft with distributed propulsion, and therefore may not require electrical redundancy.

FAA Response: The comments from Rolls-Royce and AIAB describe the potential dependency between the electric engine safety analysis and certain aircraft configurations, and the potential effect the aircraft design could have on the need for engine design redundancy. However, magniX designed these engines for certain aircraft configurations that do not have special flight control capabilities, which is why the LOPC and single fault tolerance criteria from 14 CFR part 33 are adopted in these special conditions. The FAA also included “suitable for the intended aircraft application” in Special Condition no. 10(f)(1), and “as determined by the Administrator” in Special Condition no. 10(f)(2) “Engine control system failures” to constrain the use of these engines to aircraft that are designed with compatible engine safety assumptions. Therefore, the FAA did not change these special conditions as a result of this comment.

Comment Summary: TCCA commented that the FAA’s introductory text to proposed Special Condition no. 10(e), “Environmental limits,” indicated that the environmental limits are addressed in DO-160G. However, TCCA suggested that some of the test specifications, methods, and categories in DO-160G might not be adequate for high-voltage systems such as the high-voltage components of this engine. TCCA suggested that the FAA modify Special Condition no. 10(e) to require

⁶ https://my.rtca.org/NC_Product?id=a1B36000001IcJTEAS.

⁷ https://my.rtca.org/NC_Product?id=a1B36000001IcnSEAS.

⁸ https://www.faa.gov/documentLibrary/media/Advisory_Circular/AC_33_28-3.pdf.

that the applicant establish and demonstrate the environmental limits of the engine for those circumstances when the standards in DO-160G may not be adequate.

FAA Response: These special conditions are applicable to this applicant's project and are not generally applicable requirements. As such, the FAA will evaluate the approach that the applicant proposes to substantiate the compliance of their design's high-voltage systems. The FAA made no changes to these special conditions as a result of this comment.

Comment Summary: TCCA noted that in the introduction to proposed Special Condition no. 10(f), the FAA stated that "As with other topics within these proposed special conditions, the failure rates that apply to electric engines were not established when the FAA issued this AC" [referring to AC 33.28-3]. TCCA stated that the referenced FAA guidance document might not have sufficient data to allow an applicant to substantiate the selected failure modes and failure rates applicable to the electrical engine and associated high-voltage systems. TCCA recommended that the FAA clarify the statement in the discussion and note that the applicant has the responsibility to substantiate the failure modes and rates to show compliance to these special conditions.

FAA Response: The FAA added clarification to the discussion of Special Condition no. 10(f).

Comment Summary: TCCA asked the FAA to clarify whether the engine cockpit controls are part of the configuration discussed in Special Condition no. 10. TCCA also recommended that the FAA require the applicant to conduct a human error assessment to mitigate the effects of crew mistakes due to electric engine cockpit controls if they are different from conventional engine cockpit controls.

FAA Response: The engine cockpit controls are not part of the engine configuration. No changes to these final special conditions are required to address TCCA's comment.

Comment Summary: TCCA requested that Special Condition no. 10(a) use similar wording as 14 CFR 33.28(a). TCCA stated that such wording could affect the applicant's understanding of the requirement because the proposed words indicate Special Condition no. 10(a) could also be applicable to a system or a device that is not part of the engine type design.

FAA Response: In these final special conditions, the FAA has modified Special Condition no. 10(a) to

incorporate the purpose of 14 CFR 33.28(a).

Comment Summary: TCCA stated proposed Special Condition no. 10(j) requires that the loss, malfunction, or interruption of the electrical power to the engine control system not result in a hazardous engine effect, the unacceptable transmission of erroneous data, or continued engine operation in the absence of the control function. TCCA stated that this special condition does not require the engine control system to be capable of resuming normal operation when the electrical power returns to a normal state. TCCA commented that the electrical power source could be subject to transients resulting in a temporary effect on the output power and shut down the control system and/or engine. TCCA explained once the temporary transients cease, the engine control system should be capable of resuming normal operation when the power characteristics return to the normal range (similar to the requirements of (14 CFR) 33.28(i)(4)). TCCA proposed adding a subparagraph to Special Condition no. 10(j) to require, "Voltage transients outside the power-supply voltage limitations declared in SC 10(j)(2) must meet the requirements of SC no. 10(j)(1). The engine control system must be capable of resuming normal operation when electrical power returns to within the declared limits."

FAA Response: A special condition is not required to specify requirements for voltage transients that are outside the power-supply voltage limitations declared in Special Condition no. 10(j)(2), "Engine control system electrical power" because exceedances to these limitations are addressed by Special Condition no. 10(h), "Protection systems." Special Condition no. 10(j)(1) corresponds to 14 CFR 33.28(i), which includes the additional requirement TCCA recommended. The FAA added, "The engine control system must be capable of resuming normal operation when aircraft-supplied power returns to within the declared limits" to Special Condition no. 10(j)(1) as a result of this comment.

Comment Summary: TCCA stated Special Condition no. 10 is similar to the current 14 CFR 33.28 requirement. TCCA suggested modifying Special Condition no. 10 to state, "The engine design must comply with 14 CFR 33.28."

FAA Response: 14 CFR 33.28 is applicable to reciprocating and turbine aircraft engines. The airworthiness regulations in 14 CFR 33.28 do not contain adequate or appropriate safety standards for the magni350 and magni650 model engines because of a

novel or unusual design feature (use of electrical energy source instead of aviation fuel to drive the mechanical systems). Section 33.28 contains design requirements that do not apply to the proposed engines. The FAA did not change these special conditions as a result of this comment.

Comment Summary: TCCA recommended that Special Condition no. 10(j) require the applicant to define and declare, in the engine installation manual, the characteristics of the electrical power supplied to the engine control system, as required by 14 CFR 33.28(i)(3).

FAA Response: The FAA has added a subparagraph to Special Condition no. 10(j) "Engine control system electrical power," which requires magniX to identify and declare the characteristics of any electrical power supplied from the aircraft to the engine control system for starting and operating the engine, including transient and steady-state voltage limits, and any other characteristics necessary for the safe operation of the engine in the engine installation manual.

Comment Summary: TCCA recommended that Special Condition no. 10 require a means to shut the engine down rapidly.

FAA Response: Special Condition no. 17(d)(2) incorporates 14 CFR 33.75(g)(2)(vii), which includes, as a hazardous engine effect, the complete inability to shut the engine down. The FAA made no changes to these special conditions as a result of this comment.

Comment Summary: TCCA commented that the proposed special conditions do not address the emerging issue of cybersecurity. Since the FAA is currently addressing this issue with an issue paper, TCCA recommended incorporating the issue paper into Special Condition no. 10 by reference.

TCCA also recommended that the FAA address cybersecurity by adding a special condition that states, "Information system security protection. Engine control systems, including networks, software, and data, must be designed and installed so that they are protected from intentional unauthorized electronic interactions (IUEI) that may result in adverse effects on the safety of the aircraft. The security risks and vulnerabilities must be identified, assessed, and mitigated as necessary. The applicant must make procedures and instructions for continued airworthiness (ICA) available that ensure that the security protections of the engine controls are maintained."

FAA Response: The FAA does not agree with the comment. A special condition for cybersecurity is not

needed for the magniX engine design. Cybersecurity issues are not specific to these magniX engines and will be addressed by other compliance determinations. The FAA made no changes to these special conditions as a result of this comment.

Comment Summary: Wisk stated that the change in wording from 14 CFR 33.28 from “Operating limits” to “Operating limitations” could have uncertain impacts, as “limits” are typically parametric-based and mostly achievable by a control system if so required. Wisk noted that operating limitations are more aligned to what is found in an airplane flight manual, so this expands the scope of what the control system may be expected to do.

FAA Response: The FAA has changed “operating limitations” to “operating limits” in Special Condition no. 10(b).

Comment Summary: Wisk asked what the FAA meant by “be single fault tolerant, as determined by the Administrator” in proposed Special Condition no. 10(f)(2).

FAA Response: The term “single fault tolerant” describes an engine control system’s ability to experience single failures and not result in a hazardous engine effect while operating without any fault conditions present and in all dispatchable configurations. Special Condition no. 10(f)(2) requires the engine control system to be single fault tolerant for electrical, electrically detectable, and electronic failures involving LOPC events. The FAA made no changes to these special conditions as a result of this comment.

Comment Summary: Wisk asked that the FAA clarify the meaning of “local events” as used in proposed Special Condition no. 10(f)(4) “Engine control system failures.”

FAA Response: The term “local events” used in Special Condition no. 10(f)(4) means failures or malfunctions that could lead to hazardous effects such as fire, overheat, or failures causing damage to engine control system components. The FAA made no changes to these special conditions as a result of this comment.

Comment Summary: Wisk suggested that the FAA not impose proposed Special Condition no. 10(g), “System safety assessment.” Wisk stated that the condition was unnecessary and could lead to uncertainty because 14 CFR 33.75(a), *Safety analysis*, is more rigorous. Wisk suggested incorporating § 33.75(a)(1) into Special Condition no. 10, or linking Special Condition no. 17 to Special Condition no. 10(g).

FAA Response: Special Condition no. 17 (Safety Analysis), incorporates 14 CFR 33.75(a)(1), which requires the

applicant to analyze the engine, including the control system, to assess the likely consequences of all failures that can reasonably be expected to occur. Special Condition no. 10, which is adopted as proposed, contains a separate requirement for the engine control, including the frequency of occurrence of faults or failures. The linkage requested by Wisk between the engine safety analysis and control system safety assessment exists in these special conditions. The FAA made no changes to these special conditions as a result of this comment.

Comment Summary: Wisk stated they understood the initial intent of § 33.28(i) around engine controllers being reliant on electrical power for function, whereby fuel was used for the production of useful thrust/power. Wisk commented that by stating the engine control must accommodate any ‘malfunction’ of the electrical supply forces the engine control to accommodate overvoltage, overcurrent, etc., that may drive unnecessary cost and weight on the engine manufacturer. Wisk recommended consideration is given to the high-voltage electrical source used for thrust/power generation such that it is treated more like fuel, which is under the control of the airframe OEM.

FAA Response: Special Condition no. 10(j) does not require the magniX engine controller to accommodate malfunctions of the electrical supply. The special condition requires the engine control system to be designed such that a loss, malfunction, or interruption of the control system electrical power source will not result in hazardous engine effects. However, Special Condition no. 2 requires magniX to establish and declare ratings and operating limits based on power-supply requirements for the engine, which addresses the suggestion proposed by Wisk. The FAA did not change this special condition as a result of this comment.

Comment Summary: Ampaire asked the FAA to incorporate additional information from ASTM F3338–18 section 5.10, EPU Controls, into Special Condition no. 10(g), system safety assessment, and Special Condition no. 10(h), protection systems.

FAA Response: ASTM F3338–18 contains technical criteria that the FAA incorporated in these special conditions. It also contains information that the applicant can use to develop a means of compliance to these special conditions. The FAA did not change these special conditions as a result of this comment.

Comment Summary: AIAB proposed that the FAA mandate compliance with

14 CFR 33.28(h)(2). AIAB stated that the accommodation strategy could depend on the aircraft that use the engines because the aircraft’s response to a change to thrust or power will determine if the accommodation strategy is acceptable. AIAB asked that the FAA require the applicant to evaluate the effects of aircraft-supplied data failures and document them in the engine installation manual.

FAA Response: As a result of this and other comments, the FAA modified Special Condition no. (10)(g) by adding, “The intended aircraft application must be taken into account to assure the assessment of the engine control system safety is valid.” Therefore, the applicant’s fault accommodation strategies will need to account for the aircraft’s capabilities. If the accommodation strategy meets any criteria in 14 CFR 33.5, that regulation will prompt magniX to document the details in the Instruction manual for installing and operating the engine. The FAA has changed the special condition to include additional requirements for aircraft-supplied data consistent with the recommendation.

Comment Summary: An anonymous commenter inquired if these special conditions would address electromagnetic interference potential, which, the commenter states, has caused issues with onboard radios and equipment.

FAA Response: Special Condition no. 10(e), Environmental limits, addresses potential engine effects from HIRF and lightning, as well as electromagnetic compatibility between the engine and aircraft systems. This special condition also requires the applicant to document the environmental limits to which the system has been qualified and the electromagnetic emissions from the engine. The FAA made no changes to these special conditions as a result of this comment.

Comment Summary: Textron stated the proposed Special Condition no. 10(h) matches the requirements of § 33.28(f)(1), but the requirements of § 33.28(f)(2) and (f)(3) are not included. Textron also stated there is no obvious reason why the same requirements for overspeed protection would not also apply to an electric engine, so those requirements should be added to the proposed special condition.

FAA Response: These special conditions are applicable only to the magniX magni350 and magni650 model engines. Special condition 10(h) ensures the magniX operating limits will not be exceeded in-service. The FAA made no changes to these special conditions as a result of this comment.

Comment Summary: Textron recommended that the FAA add the following to the end of Special Condition no. 10(b), “including in failure conditions where the fault or failure results in a change from one control mode to another, from one channel to another, or from the primary system to the back-up system.” Textron reasoned that 14 CFR 33.28(c) addresses failures resulting in changes to the operation of the engine and that regulatory requirements should be applicable to electric engines.

FAA Response: Special Condition no. 10 (Engine control systems) addresses the potential for all control system failures and failure effects, including failure or malfunction during control system transitions during a rotor overspeed. However, in these final special conditions, the FAA has changed Special Condition no. 10(b) as a result of this comment to include failure conditions where the fault or failure results in a change from one control mode to another, from one channel to another, or from the primary system to the back-up system, if applicable.

Special Condition No. 11, Instrument Connection

The FAA proposed that Special Condition no. 11 would require magniX to comply with 14 CFR 33.29(a), (e), (f), and (g), and, as part of the required system safety assessment, assess the possibility and subsequent effect of incorrect fit of instruments, sensors, or connectors.

Comment Summary: Wisk referred to the statement, “In addition, as part of the system safety assessment of Special Condition no. 10(g)” and recommended that the FAA replace the citation in Special Condition no. 11 with reference to Special Condition no. 17 or 14 CFR 33.75(a)(1).

FAA Response: Special Condition no. 10(g) requires a separate safety assessment for the engine control system. The engine control system safety assessment is not addressed by Special Condition no. 17 or 14 CFR 33.75(a)(1), which requires an engine-level safety analysis. The engine-level safety analysis does not go into enough detail to address the effects of control system failures and malfunctions. The FAA did not modify this special condition as a result of this comment.

Comment Summary: Textron stated, Special Condition no. 11 mandates compliance with 14 CFR 33.29(f), thereby requiring the applicant to assess the possibility and subsequent effects of incorrect fit of instruments, sensors, or connectors. Textron considered this

requirement to repeat the assessments required by Special Condition no. 10(g) (Engine control systems). For this reason, Textron recommended removing the provisions in Special Condition no. 11 that are adopted by reference to § 33.29(f).

FAA Response: Special Condition no. 10(g) corresponds to § 33.28(e), which requires an engine control systems safety assessment. However, § 33.29(f) requires that, as part of the System Safety Assessment of § 33.28(e), the applicant must assess the possibility and subsequent effect of incorrect fit of instruments, sensors, or connectors. Therefore, Special Condition no. 11 does not repeat the requirements in Special Condition 10(g). After reviewing Textron’s comment, the FAA removed reference to § 33.29(f) because the content of that regulation is captured within Special Condition no. 11(a). The FAA made no changes to the special condition as a result of the comment.

Comment Summary: TCCA recommended that the FAA add a provision requiring that instrument or sensor connections be designed or labeled to ensure a correct connection.

FAA Response: The FAA does not agree with the comment. Special Condition no. 11 applies 14 CFR 33.29(a) to the magniX engines, so this special condition already requires that the connections meet the criteria specified in TCCA’s comment. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: TCCA recommended adding the following to Special Condition no. 11: “Any instrumentation on which the Safety Analysis (see special condition no. 17) depends must be specified and declared mandatory in the engine installation manual.”

FAA Response: The certification basis for the proposed engines includes 14 CFR 33.5(a)(6), 33.5(c), and Special Condition no. 17(c), which encompasses § 33.75(d) and § 33.75(e). These requirements will achieve the desired results recommended in this comment. The FAA did not change these special conditions as a result of this comment.

Special Condition No. 12, Stress Analysis

14 CFR 33.62 requires a stress analysis be performed on each turbine engine. The requirement is applicable only to turbine engines and turbine engine components, and therefore, is not appropriate for the magni350 and magni650 Model engines. The FAA proposed this special condition due to the need for a stress analysis of similar

components used in these proposed engines.

The FAA proposed that Special Condition no. 12 would require a mechanical, thermal, and electromagnetic stress analysis that showed a sufficient design margin to prevent unacceptable operating characteristics. Also, the condition proposed to require the applicant to determine the maximum stresses in the engine by tests validated analysis, or a combination thereof and show that they do not exceed minimum material properties.

Comment Summary: Wisk asked the FAA to clarify this special condition by declaring the types of failure effects that the special condition addresses. Wisk stated that Special Condition no. 12 refers to “unacceptable operating characteristics” and that this term, coupled with Special Condition no. 9, may leave a gap where no analysis is required for static structural components (mounts, casings, etc.), which would not affect operating characteristics but could still be hazardous.

FAA Response: The corresponding 14 CFR part 33 airworthiness requirement for this special condition is § 33.62 *Stress analysis*. The corresponding part 33 airworthiness requirement for Special Condition no. 9 (Overspeed) is § 33.27, *Turbine, compressor, fan, and turbosupercharger rotor overspeed*. These special conditions are intended to apply similar requirements to the magniX engines but with additional provisions to account for electric engine technology. The additional analysis suggested in Wisk’s comment is already required by Special Condition no. 13 (Critical and life-limited parts). It requires a stress analysis of static engine parts, so no changes were made to this special condition as a result of this comment.

Comment Summary: TCCA recommended that the FAA require the applicant to provide an analysis of electromagnetic stresses.

FAA Response: The FAA concurs with this comment. The FAA has modified Special Condition no. 11 to require the analysis to assess the impact of electromagnetic interference on stress.

Comment Summary: TCCA recommended adding, “The sufficient design margin must be established in the means of compliance” to Special Condition no. 12(a).

FAA Response: Design margin is already required by Special Condition no. 12 (Stress Analysis), which will require magniX to develop the compliance documents suggested by

TCCA. In addition, design margins are also required by Special Condition nos. 9 (Overspeed), 12 (Stress Analysis), 19 (Liquid Systems), 24 (Temperature Limit), and 30 (Containment). No changes have been made to this special condition as a result of this comment.

Special Condition No. 13, Critical and Life-Limited Parts

The FAA proposed that Special Condition no. 13 would require magniX to show whether rotating or moving components, bearings, shafts, static parts, and non-redundant mount components should be classified, designed, manufactured, and managed throughout their service life as critical or life-limited parts.

Special Condition no. 13 corresponds to 14 CFR 33.70, *Engine life-limited parts*, which is a complex requirement. Accordingly, additional information is provided in this discussion. In this context, the engineering plan referenced in Special Condition no. 13(b)(1) requires magniX to establish activities for managing documents, practices, and procedures that govern essential design criteria essential to part airworthiness. The engineering plan contains methods for verifying the characteristics and qualities assumed in the design data. The methods must be suitable for the part criticality. The engineering plan communicates information from engineering to manufacturing about the criticality of design features that affect airworthiness. In accordance with 14 CFR 21.137, *Quality system*, the plan must include a reporting system that flows problematic issues that develop while operating in-service so the applicant's design process can address them. The engineering plan is established during pre-certification activities and executed during post-certification activities.

For example, the effect the environment has on engine performance might not be consistent with the design assumptions. The impact of ice slab ingestion on engine parts might not be fully understood until the engine response is evaluated during testing the specific ice quantities and shapes that the airplane sheds.

The term "low-cycle fatigue," as referenced in Special Condition no. 13(a)(2), is a decline in material strength from exposure to cyclic stress at levels beyond the stress threshold the material can sustain indefinitely. This threshold is known as the material endurance limit. Low-cycle fatigue typically causes a part to sustain plastic or permanent deformation during the cyclic loading and can lead to cracks, crack growth, and fracture. Engine parts that operate at

high-temperatures and high-mechanical stresses simultaneously can experience low-cycle fatigue coupled with creep. Creep is the tendency of a metallic material to permanently move or deform when exposed to the extreme thermal conditions created by hot combustion gasses and substantial physical loads such as high rotational speeds and maximum thrust. Conversely, high-cycle fatigue is caused by elastic deformation, small strains caused by alternating stress, and a much higher number of load cycles compared to the number of cycles that cause low-cycle fatigue.

The term "manufacturing definition," as referenced in Special Condition no. 13(b)(2), means the collection of data required to translate documented engineering-design criteria into physical parts and verify that the parts comply with the design data properties. Because FAA regulations do not require parts to fail during a certification program, the documents and processes have outcome expectations, required by 14 CFR 21.137, *Quality system* and 14 CFR 21.138, *Quality manual*, to result in parts with the integrity and reliability assumed in the design data. These production and quality systems limit the potential manufacturing outcomes to parts that are consistently produced within physical design constraints.

The manufacturing plan and service management plan ensure essential information from the engineering plan, such as the design characteristics that ensure the integrity of critical and life-limited parts, is consistently produced and preserved over the lifetime of those parts. The manufacturing plan includes special processes and production controls to prevent manufacturing-induced anomalies, which can degrade the part's structural integrity. Examples of manufacturing-induced anomalies are material contamination, unacceptable grain growth, heat affected areas, and residual stresses. The service management plan has provisions for enhanced detection and reporting of service-induced anomalies that can cause the part to fail before reaching its life-limit or service limit. Abnormalities can develop in-service from improper handling, unforeseen operating conditions, and long-term environmental effects. The service management plan ensures important information that might affect the design process's assumptions is incorporated into the design process to remove unforeseen potential unsafe features from the engine.

Comment Summary: Wisk stated it is more appropriate to use "The Applicant" than the Company name "magniX" in Special Condition no.

12(b)(1). Wisk recommended changing the reference to the engine manufacturer reference from "magniX" to "the applicant."

FAA Response: The FAA understands Wisk's comment to be relevant to Special Condition no. 13(b)(1) because Special Condition no. 12(b)(1) does not exist. These special conditions are not applicable to all electric engine manufacturers. As stated in this preamble, these special conditions apply to the magniX magni350 and magni650 model engines. No change to this special condition is necessary as a result of this comment.

Comment Summary: Textron recommended that the post-certification activities described in the Discussion section of the proposed special conditions be included in the text of Special Condition no. 13.

FAA Response: The Discussion for this special condition is based on its similarity to 14 CFR 33.70, *Engine life-limited parts*. No change to this special condition is necessary as a result of this comment.

Comment Summary: An individual commenter suggested there might be unique questions regarding low-cycle fatigue (LCF) of components used in electric engines. The commenter explained that if the core rotor speed is low, the risk of a rotor burst might not be significant. However, a core rotor assembly that uses windings or embedded permanent magnets (if applicable) may have some LCF/thermal/electrical (refer to corona effect on motor windings) cycling challenges and the electrically powered electronics driving the motor. The individual also stated that they have learned through experience about the significance of thermal effects resulting from a broad range of operating conditions, especially during quick power transients.

FAA Response: Special Condition no. 13 requires magniX to determine the parts and components that should be classified designed, manufactured and managed throughout their service life as critical or life-limited parts. Therefore, Special Condition no. 13 provides the requirements for magniX to address the unique issues that arise when identifying and managing life-limited and critical electric engine parts. The FAA made no changes to these special conditions as a result of this comment.

Comment Summary: TCCA stated that 14 CFR 33.70 is similar enough to proposed Special Condition no. 13 that the FAA should replace the proposed special condition with reference to the 14 CFR part 33 requirement and modify it. EASA suggested the FAA remove the

term “Critical Parts” from this special condition.

FAA Response: Section 33.70 prescribes a mandatory replacement interval for turbine engine parts that are likely to fail from fatigue if they are not removed from service. The failure can cause a hazardous engine effect. Section 33.70 does not address parts that have a different primary failure mode than fatigue but can still fail in a way that causes a hazardous engine condition. Electric engine technology operates using electromagnetic technology and physical properties that are different than those of turbine engines. This is why the special condition has requirements for “critical” parts. Therefore, there is a need for a special condition that addresses failures of parts and components caused by the properties related to the novel technology used in these proposed engines. Further, the FAA currently uses the term “critical parts” to describe certain parts approved under 14 CFR part 21 subpart K, *Parts Manufacturer Approval* and in 14 CFR part 35, *Airworthiness Standards: Propellers*. The use of the term “critical parts” in these special conditions is consistent with the FAA’s use of the term as it applies to conventional engines. The FAA did not change these special conditions as a result of these two comments.

Comment Summary: TCCA asked that these special conditions define “primary failure” as failures that are not the result of a prior failure of another part or system.

FAA Response: The term “primary failure” is used in 14 CFR 33.70, and this special condition is based on the requirements in that section. The FAA did not change these special conditions as a result of this comment, but the suggested clarification is adopted in the discussion to Special Condition no. 17.

Comment Summary: AIAB proposed that the FAA require the assumptions used by the applicant in the life-limited parts analysis to be declared in the engine installation manual, should the FAA certify the engine with no associated aircraft.

FAA Response: Final Special Condition nos. 10(g) and 17(e) require magniX to account for the intended aircraft application for the engine safety analysis and engine control systems safety assessment to be valid, so there will be no need to account for engines with no associated aircraft. Special Condition no. 13, Critical and life-limited parts, requires magniX to show, by safety analysis or means acceptable to the Administrator, whether rotating or moving components, bearings, shafts,

static parts, and non-redundant mount components should be classified, designed, manufactured, and managed throughout their service life as critical or life-limited parts. The assumptions used by magniX in the life-limited parts analysis are design data that provide information for compliance to Special Condition no. 13. The installers and operators of the magniX engines do not use these assumptions, and therefore, the assumptions do not need to be included in the installation manual. The FAA made no changes to this special condition as a result of this comment.

Special Condition No. 14, Lubrication System

The FAA proposed that Special Condition no. 14 would require that the lubrication system of these engines be designed to function properly between scheduled maintenance intervals and prevent engine bearing and lubrication system contamination. The FAA also proposed to require magniX to demonstrate the unique lubrication attributes and functional capability of the magni350 and magni650 Model engines.

Comment Summary: Wisk recommended removing the reference to “particle debris” from Special Condition no. 14(b), and replacing it with “The lubrication system must be designed to prevent unacceptable contamination of the engine bearings.”

FAA Response: The FAA has changed Special Condition no. 14 to specify the lubrication system must prevent any unacceptable contamination of the engine bearings. The FAA has changed the special condition as a result of this comment.

Comment Summary: TCCA recommended that Special Condition no. 14 require magniX to declare, in the engine installation manual, any reliance upon assumed installation conditions or installation requirements.

FAA Response: Special Condition no. 1 requires magniX to comply with 14 CFR 33.5, *Instruction manual for installing and operating the engine*. Section 33.5(a)(5) includes the additional requirement recommended by TCCA. The FAA made no changes to the special condition as a result of the comment.

Special Condition No. 15, Power Response

The FAA proposed that Special Condition no. 15 would require the design and construction of these engines and their control systems to enable an increase (1) from the minimum power setting to the highest-rated power without detrimental engine effects and

(2) from the minimum obtainable power while in-flight and on the ground to the highest-rated power within a time interval for the safe operation of the aircraft.

Comment Summary: Wisk recommended including the engine control system as part of the engine in these requirements. They suggest adding “and its control system” to this special condition to read, “The design and construction of the engine and its control system must enable an increase.”

FAA Response: The FAA has modified Special Condition no. 15 in these final special conditions to incorporate “including its control system” in response to the comment.

Comment Summary: Ampaire recommended that the FAA add a requirement to these special conditions that correspond to ASTM F3338–18, section 5.20.9.

FAA Response: The FAA added Special Condition no. 15(c) in the final special condition, which incorporates criteria from ASTM F3338–18, section 5.20.9.

Comment Summary: Textron commented that electrical motors could produce significantly more torque than reciprocating or turbine engines. Textron said that unregulated application of torque could be detrimental to the flight characteristics of the aircraft or the structural components of the aircraft. Textron recommended supplementing this special condition with the following requirement: “(c) of torque without detrimental engine or aircraft effects. Aircraft components must be designed to withstand the unregulated application of torque, or the application of torque should be controlled to ensure aircraft structural integrity or aircraft aerodynamic characteristics are not exceeded.”

FAA Response: The FAA agrees that electric engines produce torque differently than turbine engines. The potential for high torque values is attributable to the novel technology used in magniX’s proposed engines. Therefore, final Special Condition no. 15 has changed to include a requirement that prevents engine torque from causing detrimental aircraft effects.

Comment Summary: TCCA recommended that the FAA revise Special Condition no. 15(b), from “a time interval for the safe operation of the aircraft” to “a time interval that is determined to be safe for aircraft operation.”

FAA Response: The FAA finds that the recommended revision would be beneficial and consistent with the

change the FAA made to Special Condition no. 10(g) and the addition to Special Condition no. 17(e), which requires magniX to take into account the intended aircraft application in the engine installation manual. The FAA has changed final Special Condition no. 15(b) in the manner requested by this comment.

Comment Summary: TCCA recommended that the special condition should state the power-lever movement interval, and that response times in 14 CFR 33.73 should apply to the magniX engines, unless magniX substantiates different values for the power-lever movement interval and response times for the aircraft that will use the engines. TCCA also recommended adapting the existing § 33.73 requirement to remove the condition only applicable to the turbine engine, such as surge, stall.

FAA Response: The FAA does not agree with the comment. These special conditions are applicable only to the magniX engines. Special Condition no. 10 (Engine control systems) and Special Condition no. 17 (Safety analysis) require magniX to account for the aircraft that can use these engines. Therefore, the required power-lever movement interval and response times account for the aircraft safety objectives. Also, Special Condition no. 15 was developed to be a performance-based version of § 33.73, so all requirements of § 33.73 are not part of the special condition. The FAA did not change these special conditions as a result of this comment.

Special Condition No. 16, Continued Rotation

The FAA proposed that Special Condition no. 16 would prohibit any hazardous engine effects to result from the continued rotation of engine rotating systems that the design allows to rotate after the engine is shut down.

Comment Summary: Textron stated that there is potential for electric engines to regenerate electric energy from continuing to freely rotate after the engine is shut down, and recommended an additional requirement to prevent hazardous electrical bus effects.

FAA Response: These special conditions apply only to the subject magniX engines, which are not intended to regenerate or otherwise direct electrical power to the aircraft. The FAA made no changes to the special condition as a result of the comment.

Special Condition No. 17, Safety Analysis

The FAA proposed that Special Condition no. 17 would require magniX to comply with 14 CFR 33.75(a)(1),

(a)(2), and (a)(3), which require an applicant to conduct a safety analysis of the engine, and which would otherwise apply only to applications for turbine aircraft engines. Additionally, the proposed special conditions would require magniX to assess its engine design to determine the likely consequences of all failures that can reasonably be expected to occur, and state, in the safety analysis, the failure of such elements and associated prescribed integrity requirements.

As used in Special Condition no. 17, a primary failure is a manner in which a part fails if the engine is installed in the expected aircraft configurations and operated in accordance with operating conditions assumed in the design data such as the expected performance cycles, engine limits, and operating environments, and maintained using the declared instructions for continued airworthiness. A primary failure is not the result of the prior failure of another part or system.

Some engine parts can fail suddenly in their primary failure from prolonged exposure to the physical conditions in a normal engine environment, such as temperature, vibration, and stress. The probability of failure cannot be sensibly estimated in numerical terms, and failure will likely result in a hazardous engine effect. As a result, 14 CFR 33.70, *Engine life-limited parts*, and 14 CFR 33.75, *Safety analysis*, do not allow these parts to be managed by on-condition or probabilistic means. Therefore, requirements such as life limits, scheduled inspections, and inspection techniques are mandated to ensure the essential attributes are preserved throughout the part's service life. For example, if the number of engine cycles to failure is predictable and can be associated with specific design characteristics, such as material properties, then the applicant can manage the engine part with life limits.

The safety analysis requires magniX to identify hazards that are applicable to the electric technology used in their engine design. All the engine hazards that apply to turbine engines also apply to the magniX electric engines, in addition to possible exceedances of any new engine limits pursuant to Special Condition no. 2 (Engine ratings and operating limits) to prevent failure of electronic components that have a direct impact on safety.

The outcome of the safety analysis partially depends on the aircraft types that will use these engines. Therefore, final Special Condition nos. 17(e) and 10(g) require magniX to account for the intended aircraft application in the engine installation manual to ensure the

magniX engine is installed only in aircraft with compatible safety assumptions. The term "intended aircraft application" means the aircraft that are expected to operate with the magniX engines.

Comment Summary: Regarding Special Condition no. 17(d)(3), Wisk recommended that the FAA classify a loss of partial thrust, or a thrust variation of a small amount, as a "major effect" which should be only considered when the impact is relevant at the aircraft level. Wisk also stated that the applicable 14 CFR part 23, 25, 27, and 29 regulations establish appropriate LOTC/LOPC classifications, so a special condition for 14 CFR 33.75 appears unnecessary. Wisk recommended that Special Condition no. 17(d)(1) use the existing words of § 33.75(g)(1), which state, "An engine failure in which the only consequence is partial or complete loss of thrust or power (and associated engine services) from the engine will be regarded as a minor engine effect."

FAA Response: The FAA does not agree with the comment. These special conditions are not generally applicable to electric engines. The requirements only apply to the magniX magni350 and magni650 model electric engines. The safety analysis classifies engine failures, including LOTC/LOPC. The classification LOTC/LOPC events partially depends on the aircraft types that will use these engines, so the existing engine reliability requirements and accepted partial power levels in 14 CFR part 23, 25, 27, and 29 aircraft are not directly applicable without further review of the engine and aircraft capabilities. In addition, Special Condition no. 10(f)(1) requires the LOPC rate to be suitable for the intended aircraft application; and Special Condition no. 10, including 10(f)(2), requires the Administrator to determine the need for design redundancy relating to LOPC events to ensure the magniX engine LOPC rate is compatible with the aircraft safety objectives. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: GE directed attention to the integrity requirements listed in Special Condition no. 17(b). The requirement addresses elements (engine parts, components, and systems) that can fail and are likely to result in hazardous engine effects. GE stated that the integrity requirements in Special Condition no. 17(b) are not complete and may not achieve a level of safety equivalent to that established in 14 CFR 33.75, *Safety analysis*, and 33.70, *Engine life-limited parts*. GE recommended adding a statement that requires magniX to include any other

necessary requirements to achieve the safety analysis goals. EASA provided a similar comment and recommendation.

FAA Response: In response to these comments, the FAA has changed final Special Condition no. 17(b) to ensure all the applicable integrity requirements are applied to magniX engine parts that can fail and are likely to result in hazardous engine effects.

Comment Summary: GE commented that the definitions of “major” and “minor” engine effects, as mentioned in Special Condition nos. 17(d)(1), 17(d)(2), and 17(d)(3) are ambiguous, leaving a wide gap in the failure types that could be classified as hazardous or major engine effects. GE also commented that there is no probability requirement for major engine effects like there is in 14 CFR 33.75(a)(4). GE recommended that the FAA clarify the definitions of major and minor engine effects, and include a probability requirement to ensure a level of safety commensurate with the current regulations.

FAA Response: These special conditions are not generally applicable to all electric engines. They apply only to these proposed magniX engines. The FAA acknowledges many possible outcomes to the engine safety analysis, including the failure classifications. Failure classification and probabilities for the engine and certain electronic components are still needed, but the failure classifications and reliability thresholds will account for the aircraft’s capabilities. Special Condition no. 17 does not specify the engine failure effects that could be classified as major because aircraft’s capabilities can affect the failure classification.

As a result of this comment, the FAA modified final Special Condition nos. 17(d)(1) and 17(d)(3) to clarify the differences between major and minor engine failure effects. The FAA also added final Special Condition no. 17(e) to account for the potential influence aircraft capabilities may have on the engine safety analysis.

Comment Summary: Ampaire recommended adding criteria from the industry standard ASTM F3338–18, sections 5.18.1 through 5.18.6, to Special Condition no. 17.

FAA Response: ASTM F3338–18 contains technical criteria that the FAA incorporated in these special conditions. It also contains information that the applicant can use to develop a means of compliance to these special conditions. The FAA did not change these special conditions as a result of this comment.

Comment Summary: Textron stated that electrical-component manufacturers

typically do not know how their components will be used or the implications to safety when changes are made to the design and manufacturing process. Textron recommended modifying Special Condition no. 17(c) to state: “In addition, if electrical components of a safety system are outside the control of the engine manufacturer, then the manufacturer must implement a component tracking system to monitor component revisions, change of manufacture, counterfeit parts, and component end of life (EOL).”

FAA Response: Textron’s comment identified a need for engine-level configuration control. The FAA acknowledges that a product’s end-user could affect the intended engine configuration through parts manufacturer approvals and supplemental type certificates. However, the FAA imposed Special Condition no. 1, which mandates magniX’s compliance with 14 CFR 33.5(a)(5), 33.5(c), and 33.75 (d) to manage non-OEM engine configurations. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: Safran noted that Special Condition no. 17(a) requires magniX to comply with 14 CFR 33.75(a)(3), which establishes a fixed numerical value of 10^{-7} per flight hour for “extremely remote,” a number that might exceed the aircraft safety objectives. For example, “extremely remote” for a part 23/Level 1 aircraft application is rated at 10^{-5} per flight hour, not 10^{-7} . EASA shared Safran’s concern and recommended that the FAA use the EASA SC E–18⁹ to establish engine safety objectives that are proportional to the safety objectives of the intended aircraft when they are equipped with the magniX engines.

FAA Response: Both comments presume the general applicability of the proposed special conditions. These special conditions apply only to magniX’s two proposed engine models. The aircraft that will use the magniX engines do not include Part 23/Level 1 aircraft. However, the FAA acknowledges that acceptable engine failure rates could vary depending on the aircraft’s configuration and capabilities. Therefore, the FAA removed reference to § 33.75(a)(3) from Special Condition no. 17(a). Also, The FAA changed final Special Condition no. 10(g) and added Special Condition

no. 17(e) to require magniX to account for the intended aircraft application.

Comment Summary: TCCA stated the term “electrocution” is defined as “to kill with electricity” and recommended that the FAA change the term “electrocution” in this special condition to “electric shock” or “injury from electric shock.”

FAA Response: The FAA does not agree with the comment. The term “electrocution,” as used in these special conditions, is consistent with the risk of serious injury or fatality caused by electric shock.

Comment Summary: TCCA asked the FAA to explain why proposed Special Condition no. 17 did not include the requirement for major failure rates in 14 CFR 33.75(a)(4).

FAA Response: To account for the potential dependency between the electric engine safety analysis and the aircraft capabilities, the FAA did not prescribe failure rates for major engine failures. Special Condition no. 10(g) and Special Condition no. 17(e) require magniX to account for the intended aircraft application. magniX will still need to classify major failures for the engine and certain electronic components, but the failure rates will account for aircraft capabilities. The FAA has changed the special condition as a result of this comment.

Comment Summary: TCCA asked the FAA to consider requiring the applicant’s safety analysis to analyze uncontrollable high thrust and potential physical separation of the engine from the aircraft.

FAA Response: The FAA understands TCCA’s reference to “uncontrollable” high thrust to mean a higher thrust than the commanded thrust or a thrust that is above a limit value. Special Condition no. 10(f)(1) requires a maximum LOPC rate for the intended aircraft that will use the magniX engines, and magniX will need to show how they comply with those rates. Special Condition no. 17(d)(2) requires magniX to comply with 14 CFR 33.75(g)(2)(v), which addresses the physical separation of the engine from the aircraft. The FAA did not change this special condition as a result of this comment.

Comment Summary: TCCA suggested that the FAA require magniX to show that a cooling loss will not result in a hazardous engine effect or that blockage cannot lead to a cooling failure. TCCA’s comment was directed to Special Condition no. 18 in the context of protecting the cooling inlet from ingestion.

FAA Response: In response to TCCA’s comment, the FAA has included a requirement in Special Condition no.

⁹ https://www.easa.europa.eu/sites/default/files/dfu/sc_e-18_electric_propulsion_units_for_cs-23_normal-category_aeroplanes_u.pdf.

17(d)(2)(ii) to prevent hazardous engine effects from cooling blockage.

Comment Summary: EASA commented that the special condition has no proposed safety objectives for major failure conditions. EASA recommended that the FAA use the approach of EASA SC E-19¹⁰ that requires the propulsion system to have a level of safety that allows the intended aircraft to meet its safety objectives defined in the aircraft type certification basis.

FAA Response: There are many possible outcomes to the magniX engine safety analysis, including the failure classifications. Failure classification and probabilities for the engine and certain electronic components are needed, but the failure classifications and reliability thresholds will account for aircraft capabilities. The FAA has changed final Special Condition no. 10(g) and added Special Condition no. 17(e) to require magniX to account for the intended aircraft application.

The additions to Special Condition nos. 10(g) and 17(e) allow for the aircraft safety objectives to be considered when establishing the engine failure classifications and failure rates.

Comment Summary: EASA noted the reference to Special Condition no. 9 in Special Condition no. 17(b): “If the failure of such elements is likely to result in hazardous engine effects, then the applicant may show compliance by reliance on the prescribed integrity requirements of 14 CFR 33.15, Special Condition no. 9, or Special Condition no. 13, as determined by analysis.”

EASA stated that proposed Special Condition no. 9 is insufficient for hazardous failure conditions. EASA said that a rotor growth margin is a design margin, but it does not preclude any other failure root cause of a failure, such as a production issue. EASA suggested that the FAA change these special conditions to remove this possibility.

FAA Response: The FAA agrees with the comment. There might be a need to consider additional integrity requirements to account for the potential root causes for failures of the magniX electric engine parts. The FAA has changed final Special Condition 17(b) to add “such as” before the list of integrity requirements.

Special Condition No. 18, Ingestion

The FAA proposed that Special Condition no. 18 would require magniX to ensure that these engines will not experience unacceptable power loss or

hazardous engine effects from ingestion. For example, the current bird-ingestion airworthiness regulation for turbine engines, 14 CFR 33.76, is based on potential damage from birds entering a turbine engine with an inlet duct that directs air into the engine for combustion, cooling, and thrust. In contrast, these electric engines do not use an inlet duct for those purposes. Instead, the electric engine inlet duct is primarily used to streamline the air entering the inlet for efficient cooling of internal engine components.

An “unacceptable” power loss, as stated in Special Condition no. 18(a), refers to a situation in which the power or thrust required for safe flight of the aircraft becomes unavailable to the pilot. The specific amount of power loss necessary for a safe flight depends on the aircraft configuration, speed, altitude, attitude, atmospheric conditions, phase of flight, and other circumstances, where the demand for thrust is critical to the aircraft’s safe operation.

This special condition also requires magniX to declare the ingestion sources that are not evaluated in the engine installation manual.

Comment Summary: Textron recommended that this special condition quantify the ingestion threats in a manner similar to the way they are quantified for turbine engines in 14 CFR 33.76, *Bird ingestion*, § 33.77, *Foreign object ingestion—ice*, and § 33.78, *Rain and hail ingestion*. The commenter suggested that bird numbers and sizes, ice, rain, and hail concentrations should be provided.

FAA Response: The FAA does not agree with Textron’s recommendation. A special condition is not required to quantify ingestion threats. The FAA did not change this special condition as a result of this comment.

Comment Summary: Airbus stated that while detailed means of compliance (test, analysis, etc.) need not be part of this special condition, the FAA should specify the ingestion conditions, such as icing environments, that magniX must consider in showing compliance.

FAA Response: The FAA has changed final Special Condition no. 18 to require ingestion sources, that are not evaluated by magniX, to be declared in the engine installation manual.

Comment Summary: Textron recommended that this special condition include a provision to prevent the accumulation of ferromagnetic material in the air-cooled passages, and to prevent blockages and short circuits between the rotor and the stator for non-sealed engines.

FAA Response: The FAA does not agree with this comment. The special condition requires magniX to consider ingestion of material originating from outside the engine, not from within it. The potential for ferromagnetic contamination of engine bearings from sources within the engine would not likely meet the requirements established in these special conditions, such as Special Condition nos. 5 (Durability) and 7 (Safety Analysis). The contamination is more likely a consequence of an engine failure or inadequate maintenance. The FAA made no changes to these special conditions as a result of this comment.

Comment Summary: EASA stated rain conditions are a normal flight condition, even in VFR, and should be distinguished from other ingestion phenomena. EASA recommended incorporating EASA Special Condition E-18 issue 2: “operation under rain conditions must not result in any abnormal operation (*i.e.*, shutdown, power loss, erratic operation, power oscillations, failures . . .) throughout the EPU operating range.”

FAA Response: The FAA has modified Special Condition no. 18 in response to this comment to require the magniX engine to operate safely in rain environments. The word “rain” was removed from Special Condition no. 18(a). The following special conditions were added: Special Condition no. 18(b), which provides that rain ingestion must not result in an abnormal operation such as shutdown, power loss, erratic operation, or power oscillations throughout the engine operating range, and Special Condition no. 18(d), which requires the applicant to declare, in the engine installation manual, ingestion sources that are not evaluated.

Comment Summary: EASA asked the FAA to verify the proposed Special Condition no. 18 might result in a limitation that could be established at the aircraft-level for operation in icing conditions.

FAA Response: These special conditions are not intended for all electric engine certification projects. They are intended for the magni350 and magni650 electric engines. magniX intends to pursue a type certificate for their electric engine. If magniX elects to omit likely sources of ingestion (foreign objects, birds, ice, hail) from their evaluations, Special Condition no. 18(d) requires magniX to declare ingestion sources that are not evaluated in the engine installation manual, except for rain. Special Condition no. 18(b) was added as a result of EASA’s comment to implement performance requirements in

¹⁰ <https://www.easa.europa.eu/document-library/product-certification-consultations/final-special-condition-sc-e-19-electric>.

rain conditions. No changes were made to this special condition as a result of this comment.

Special Condition No. 19, Liquid Systems

The FAA proposed that Special Condition no. 19 would require magniX to ensure that liquid systems used for lubrication or cooling of engine components are designed and constructed to function properly. Also, the FAA proposed that, if a magniX engine liquid system is shared with an aircraft liquid system, the interfaces between the engine and aircraft systems must be defined in the engine installation manual.

Comment Summary: Wisk recommended that these special conditions address the risk of a liquid system freezing after an engine shutdown and preserve the ability for engine restart.

FAA Response: These special conditions already account for the concerns expressed by Wisk. Special Condition no. 19 requires magniX to ensure the liquid system operates appropriately in all atmospheric conditions in which the engine is expected to operate. The FAA did not change Special Condition no. 19 as a result of this comment.

Comment Summary: Rolls-Royce noted that the FAA did not propose to require the design to comply with 14 CFR 33.64, *Pressurized engine static parts*. The commenter stated that it anticipated electric engine configurations with pressurized cooling systems and pressurized lubrication systems and recommended that this requirement be included in these special conditions.

FAA Response: These special conditions are not generally applicable to all electric engines and apply only to these proposed magniX electric engines. However, magniX may choose to pressurize the liquid systems in their engines. Therefore, the FAA has changed final Special Condition no. 19 to require magniX to account for pressurized static engine parts.

Comment Summary: Textron recommended that these special conditions require that the engine installation manual prescribe the cooling and lubricating fluids used on these engines.

FAA Response: The FAA has modified Special Condition no. 19 in these final special conditions to require magniX to list eligible lubricants and coolants in the engine installation manual.

Comment Summary: Textron recommended that the FAA add a

requirement that prevents magnetically attracted engine debris from accumulating in passages that could block or limit coolant flow.

FAA Response: The potential for magnetic debris in the magniX engine liquid cooling system would likely be a consequence of an engine failure or inadequate maintenance. If this were a characteristic of the type design, the magniX engines would not likely meet the requirements established in these special conditions, such as Special Condition nos. 5 (Durability) and 7 (Safety Analysis). The FAA did not change Special Condition no. 19 as a result of this comment.

Comment Summary: TCCA noted the possibility that the magniX electric engine liquid system might rely on aircraft systems. In that case, TCCA recommended that these special conditions require that reliance be declared in the engine installation manual.

FAA Response: Special Condition no. 1 requires magniX to comply with 14 CFR 33.5, *Instruction manual for installing and operating the engine*. The requirements in §§ 33.5(a)(5) and 33.5(c) address the safety concern raised in this comment. The FAA did not change Special Condition no. 19 due to this comment.

Special Condition No. 20, Vibration Demonstration

The FAA proposed that Special Condition no. 20 would require magniX to ensure (1) the engine is designed and constructed to function throughout its normal operating range of rotor speeds and engine output power without inducing excessive stress caused by engine vibration, and (2) the engine design undergoes a vibration survey.

Comment Summary: Wisk recommended that the FAA incorporate the requirements from 14 CFR 33.83(f), *Vibration test*, instead of proposed Special Condition no. 20(b), when the installation can be assessed by analysis to match an approved engine installation because the existing 14 CFR part 33 regulation does not appear to require a vibration survey.

FAA Response: This special condition combines the requirements of §§ 33.63, *Vibration*, and 33.83, *Vibration test*. Special Condition no. 20(a) corresponds to § 33.63, Subpart E, which has provisions for the design and construction of the electric engine. Special Condition no. 20(b) corresponds to § 33.83, Subpart F, which applies to the block tests. This § 33.83, *Vibration test*, reference explains why a vibration survey is specified in Special Condition no. 20(b) and not in 20(a). In addition,

the special condition requires magniX engines to undergo a vibration survey using test, validated analysis, or a combination of both. Therefore, this special condition addresses Wisk's comment. The FAA did not change this special condition as a result of this comment.

Comment Summary: Ampaire suggested the terminology used in the title of proposed Special Condition no. 20 described a "vibration demonstration," and the term used in the ASTM document referred to the requirement as a "test" (ref. ASTM F3338–18, section 5.20.4).

FAA Response: A demonstration is a test, but this special condition also allows validated analysis to show compliance. A test is required to validate an analysis, so the requirement is grounded in a test. The FAA did not change this special condition as a result of this comment.

Comment Summary: TCCA stated that paragraph (a) of proposed Special Condition no. 20 is similar to 14 CFR 33.83(b), which has a demonstration element. TCCA asked that the FAA clarify when to use representative propeller loads during engine testing. TCCA also recommended the FAA add clarification within Special Condition no. 20 to explain when propeller loads are required during the engine demonstrations.

FAA Response: Special Condition no. 20 has a demonstration element. Special Condition no. 20(a) corresponds to 14 CFR 33.63 in Subpart E, *Design and Construction; Turbine Aircraft Engines*, and Special Condition no. 20(b) corresponds to § 33.83 in Subpart F, *Block Tests; Turbine Aircraft Engines*. TCCA's comment also relates to Special Condition no. 31, *Operation with a variable pitch propeller*, which corresponds to § 33.95, *Engine-propeller systems tests*. As a result of TCCA's comment, the FAA modified final Special Condition no. 31 to enable magniX to run their engines with a variable pitch propeller during the operation demonstration.

Comment Summary: TCCA recommended that the FAA add a requirement for magniX to evaluate the vibration effects from sustained engine unbalance to protect the engine and aircraft from vibration effects caused by engine failures that result in windmilling or propeller pitch or propeller feathering issues. TCCA recommended adding a paragraph that states, "The effects on vibration characteristics of excitation forces caused by fault conditions must be evaluated by test or analysis, or by reference to previous experience and

shown not to result in a hazardous engine effect.”

FAA Response: Special Condition no. 16 (Continued rotation) corresponds to 14 CFR 33.74, which precludes hazardous engine effects from continued rotation of engine main rotating systems after the engine is shut down for any reason while in flight. This includes the effects of vibration from failures that result in a rotor unbalance. Therefore, Special Condition no. 16 addresses the failure effects TCCA identified in their comment. The FAA did not change these special conditions as a result of this comment.

Comment Summary: TCCA recommended requiring an evaluation of vibration effects that result from excitation forces caused by fault conditions or to address these effects by reference to experience with engine failures that did not result in a hazardous engine effect. TCCA also recommended addressing the vibration effects from sustained engine unbalance.

FAA Response: Special Condition no. 16 (Continued rotation) precludes hazardous engine effects from continued rotation after the engine is shut down for any reason while in flight, including fault conditions. These special conditions are applicable to the magniX engines, which are new to aviation. Therefore, engine experience is not relevant to the magniX engine certification project. The FAA did not change this special condition as a result of this comment.

Special Condition No. 21, Overtorque

The FAA proposed that Special Condition no. 21 would require magniX to demonstrate that the engine is capable of continuous operation without the need for maintenance if it experiences a certain amount of overtorque.

Comment Summary: TCCA suggested that the FAA add the teardown inspection requirement of Special Condition no. 29 for each engine part or individual groups of components after conducting the overtorque test.

FAA Response: The additional requirement suggested by TCCA corresponds to 14 CFR 33.84(a)(2), *Engine overtorque test*. The engines proposed by magniX may require a transient maximum overtorque rating. The FAA has changed final Special Condition no. 21 to require compliance to Special Condition no. 29 (Teardown inspection) after conducting an overtorque test.

Special Condition No. 22, Calibration Assurance

The FAA received no comments for Special Condition no. 22, and it is adopted as proposed. It requires magniX to subject the engine to calibration tests, to establish its power characteristics and the conditions both before and after the endurance and durability demonstrations specified in proposed Special Condition nos. 23 and 26. The calibration test requirements specified in § 33.85 only apply to the endurance test specified in § 33.87, which is applicable only to turbine engines. The methods used for accomplishing those tests for turbine engines are not the best approach for electric engines. The calibration tests in § 33.85 have provisions applicable to ratings that are not relevant to the magniX magni350 and magni650 model engines. Special Condition no. 22 allows magniX to demonstrate the endurance and durability of the electric engine either together or independently, whichever is most appropriate for the engine qualities being assessed. Consequently, this special condition applies the calibration requirement to both the endurance and durability tests.

Special Condition No. 23, Endurance Demonstration

The FAA proposed that Special Condition no. 23 would require magniX to subject the engine to an endurance demonstration test, acceptable to the Administrator, to demonstrate the engine capabilities at the declared limits.

The FAA proposed to evaluate the extent to which the test exposes the engine to failures that could occur when the engine is operated at its rated values, to determine if the test is sufficient to show that the engine design will not exhibit unacceptable effects in-service, such as significant performance deterioration, operability restrictions, and engine power loss or instability, when run for sustained periods at extreme operating conditions.

Comment Summary: Rolls-Royce stated that the second sentence of the proposed special condition contained a typographical error and suggested that it should read, “The endurance demonstration elevates and increases the engine’s power settings, and dwells at the power settings for durations that produce the extreme physical conditions. . . .” Rolls-Royce recommended replacing “decreases” with “increases” in the special condition.

FAA Response: Final Special Condition no. 23 has been changed. The

FAA considered the change proposed by Rolls-Royce and changed the term “elevates” to “increases.”

Comment Summary: TCCA recommended that the FAA add the following three sentences to Special Condition no. 23: (1) “The severity of the demonstration should consider the design and intended use of the engine, and include the demonstration of safe operation under all operational limits to be applied during service operation of the engine.” (2) “When approval is sought for Normal Transient engine exceedances, it must be substantiated that the engine is capable of operation at the maximum engine transient condition of the affected engine parameter(s) without maintenance action.” (3) “When approval is sought for Inadvertent Transient engine exceedances, it must be substantiated that the engine is capable of operation at the maximum engine transient condition of the affected engine parameter(s) without maintenance action other than to correct any failure that led to the exceedances.”

FAA Response: The FAA does not agree to include the additions recommended by TCCA. Regarding TCCA sentence (1), adding a definition for severity in this special condition is unnecessary because this special condition is intended to achieve the same objectives as 14 CFR 33.87, *Endurance test*, but for the magniX electric engines. The test will be different for the magniX engines because those engines use electrical technology for propulsion. Whether the engine is turbine or electric, the endurance test achieves a severity that demonstrates the engine is safe to operate at its certificated limits.

Regarding TCCA sentence (2), Special Condition no. 32 requires the engine and its components to be within serviceable limits, safe for continued operation, and capable of operating at declared ratings while remaining within limits upon completing all demonstrations and testing specified in these special conditions. If the magniX engine ratings include maximum transients, the engines must demonstrate that they operate safely during the maximum transients and meet the post-test engine requirements specified in these special conditions.

Regarding TCCA sentence (3), Special Condition no. 23 is intended to assess the magniX engine’s capabilities. It is not intended to show the engine can accommodate failures and malfunctions that lead to inadvertent transients that exceed the engine’s certificated limits. Special Condition no. 17 (Safety analysis) addresses potential effects

from exceeding maximum limits and transients. Results from the safety analysis are used to decide how to manage the consequences of all failures that can reasonably be expected to occur.

Special Condition No. 24, Temperature Limit

The FAA proposed that Special Condition no. 24 would require magniX to ensure the engine can endure operation at its temperature limits, plus an acceptable margin. An “acceptable margin,” as used in this special condition, is the amount of temperature above that required to prevent the least-capable engine allowed by the type design from failing due to temperature-related causes when operating at the most extreme thermal conditions.

Comment Summary: Textron recommended that the FAA require the applicant to consider environmental conditions and that the engine temperature limit be substantiated at the worst-case environmental conditions to ensure the engine cooling system performance is adequate when the engine operates at the declared temperature limit.

FAA Response: The FAA has changed final Special Condition no. 24 with a requirement for magniX to account for operating environments when they establish a value for the engine temperature limit.

Comment Summary: TCCA recommended that Special Condition no. 24 include the following footnote: “Acceptable margin, as used in the proposed special condition, is the amount of temperature above that required to prevent the least-capable engine allowed by the type design from failing due to temperature-related causes when operating at the most extreme thermal conditions.” TCCA also recommended that Special Condition no. 24 include: “Upon completion of the demonstration, the engine must be within serviceable limits.”

FAA Response: The FAA does not agree with this comment. The following special conditions already incorporate the technical criteria proposed by TCCA:

Special Condition no. 1 requires magniX to comply with 14 CFR 33.8, *Selection of engine power and thrust ratings*, for the proposed engines. Section 33.8(b) requires that each selected rating must be for the lowest power or thrust that all engines of the same type may be expected to produce under the conditions used to determine that rating. This requirement will address the temperature margins

required for the least (thermally) capable engine the type design allows.

Special Condition no. 32(c) (General conduct of tests) has provisions that require the engine and its components to be within serviceable limits, safe for continued operation, and capable of operating at the declared ratings without exceeding limits after completing the tests identified in these special conditions.

Special Condition no. 24 requires the engine design to demonstrate its capability to endure operation at its temperature limit plus an acceptable margin.

Special Condition no. 12 (Stress analysis) includes a requirement for a thermal stress analysis to show a sufficient design margin to prevent unacceptable operating characteristics and hazardous engine effects.

Therefore, Special Condition nos. 12, 24, 32(c), and § 33.8 address TCCA’s recommendation. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: EASA commented that the temperature limit is a new requirement compared to the requirements in 14 CFR part 33, EASA CS-E’s,¹¹ and the technical criteria in ASTM F3338–18. EASA stated that the applicant demonstrates operation up to the limits as part of the endurance test. EASA further commented that the engine’s serviceability after the endurance test is sufficient proof that the engine has been designed and manufactured with margins compared to the limits declared in the engine installation manual. Therefore EASA recommended removing this requirement from this special condition.

FAA Response: The FAA does not agree with this comment. The FAA included a temperature limit because it is directly related to a primary failure mechanism associated with the novel technology used in magniX’s proposed electric engine designs. The FAA did not change this special condition as a result of this comment.

Special Condition No. 25, Operation Demonstration

The FAA proposed that Special Condition no. 25 would require that the engine demonstrate safe operating characteristics throughout its declared flight envelope and operating range. The engine performance data magniX will use to certify each engine must account for installation loads and effects.

Comment Summary: Ampaire stated that the terminology used in the

proposed special condition uses the term “demonstration,” and the term used in the ASTM document refers to the requirement as a “test” (ref. ASTM F3338–18, section 5.20.8).

FAA Response: As used in these special conditions, a demonstration is a test, but the special condition also allows validated analysis to show compliance. A test is required to validate an analysis, so the requirement is always grounded in a test. The FAA made no changes to the special condition as a result of this comment.

Comment Summary: Ampaire suggested that in-flight restart characteristics are a critical capability of electric engines and recommended that the FAA require this capability as part of the engine demonstration test. Airbus and TCCA also recommended that the FAA require a demonstration of in-flight restart capability. In addition, TCCA recommended that the special conditions require these demonstrations to be conducted with a representative propeller.

FAA Response: The FAA does not agree with the comments. Engine in-flight restart capabilities are established at the aircraft level in accordance with 14 CFR 23.2425(b), 25.903(e), 27.903(d), and 29.903(e). These regulations also require installed engines to have a restart capability within the aircraft’s flight envelope. Therefore, a requirement for magniX to verify the in-flight restart capability of their engines during the engine certification program is not within the bounds of these special conditions. No changes were made to final Special Condition no. 25 as a result of this comment.

Comment Summary: TCCA asked if a gearbox assembly is considered as a single “part” of the engine.

FAA Response: A gearbox assembly is not considered to be a single part of the magniX engine. Gearboxes used in the magniX engines are treated as an engine accessory. The 14 CFR part 33 requirements imposed by Special Condition no. 1 that address engines with gearboxes and apply to magniX engines are 14 CFR 33.3, 33.5, 33.25, and Appendix A33.3. The special conditions that correspond to 14 CFR part 33 requirements that address gearboxes used in the magniX engines are Special Condition nos. 2, 15, 20, 22, 23 and 26. No changes were made to these special conditions as a result of TCCA’s comment.

Special Condition No. 26, Durability Demonstration

The FAA proposed that Special Condition no. 26 would require magniX to subject the engine to a durability

¹¹ <https://www.easa.europa.eu/certification-specifications/cs-e-engines>.

demonstration. The durability demonstration must show that each part of the engine is designed and constructed to minimize any unsafe condition of the system between overhaul periods or between engine-replacement intervals if the overhaul is not defined.

Comment Summary: TCCA commented that these special conditions do not contain a modified 14 CFR 33.4 description of ICA for the intended electric engine applications. TCCA suggested that ICA should represent all the instructions required for the magniX engines to remain airworthy, but that instructions for off-wing maintenance instructions in the ICA would not be appropriate.

FAA Response: These special conditions are not intended for all electric engine certification projects. As required by Special Condition no. 1, magniX must comply with § 33.4, *Instructions for Continued Airworthiness*, and its appendix. These requirements are appropriate to address the maintenance requirements for these proposed engine designs. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: TCCA recommended adding 14 CFR 33.19(b), *Propeller pitch control design requirements*, to Special Condition no. 26, with an opt-out option if the magniX engines do not have propeller-blade pitch control systems.

FAA Response: These special conditions apply to the magni350 and magni650 model engines. These magniX engines do not have a propeller-blade pitch control system. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: TCCA recommended revising this special condition to state, “The engine must be subjected to a durability demonstration to show that each part of the engine has been designed and constructed to minimize any unsafe condition of the system and subsystem between overhaul periods or between engine components/parts replacement intervals. . . .”

FAA Response: magniX’s proposed engines must meet Special Condition no. 29 (Teardown inspection) requirements after completing the durability demonstration specified in this special condition. In addition, magniX must meet the requirements of Special Condition no. 32 (General conduct of tests). These special conditions, in combination with the demonstration tests required by these magniX special conditions, achieve the objectives identified by this comment. The FAA made no changes to the

special condition as a result of the comment.

Comment Summary: TCCA suggested that the FAA modify Special Condition no. 26 in a manner that results in the following revision: “This test must simulate the conditions in which the engine is expected to operate in-service, including typical start-stop cycles and scheduled maintenance actions and must be of sufficient duration in order to provide confidence in the durability of the engine.”

FAA Response: The FAA does not agree with the comment. The required durability demonstration provides information for compliance to 14 CFR 33.4, *Instructions for continued airworthiness*, which is imposed by Special Condition no. 1. If maintenance is required to complete the test, the specific maintenance actions could become part of the mandatory ICA. The discussion for Special Condition no. 32 contains more information about maintenance conducted during a test. Special Condition no. 32 (General conduct of tests) has criteria that permit some maintenance to be accomplished during the test without incurring additional mandatory ICA. The FAA agrees that the test duration can provide confidence in the engine’s durability. However, whether the test duration is long or short, magniX will develop a maintenance plan based on the test that magniX creates for their program, in accordance with § 33.4. The FAA made no changes to the special condition as a result of the comment.

Special Condition No. 27, System and Component Tests

The FAA proposed that Special Condition no. 27 would require magniX to show that the engine’s systems and components would perform their intended functions in all declared engine environments and operating conditions.

Comment Summary: TCCA recommended that the FAA require magniX to establish temperature limits for each component that requires temperature-controlling provisions in the aircraft installation to assure satisfactory functioning, reliability, and durability.

FAA Response: Other special conditions address TCCA’s concern. Special Condition no. 2 (Engine ratings and operating limits) requires magniX to establish a temperature limit that is necessary for safe operation of the engine. Whether or not a temperature limit is established for a component depends on the outcome of Special Condition no. 17 (Safety analysis), which examines the consequence of

engine failure from high-temperature. If cooling is required to satisfy Special Condition no. 17 (Safety analysis), the cooling system monitoring features and usage are documented in accordance with § 33.5(c), *Safety analysis instructions*. The FAA did not change this special condition as a result of this comment.

Comment Summary: TCCA recommended that the FAA require magniX to establish voltage and current limits “for each component that requires voltage or current controlling provisions, or both, in the aircraft installation to assure satisfactory functioning, reliability, and durability.”

FAA Response: Other special conditions address TCCA’s concern. Regarding voltage and current limits, Special Condition no. 2 requires magniX to establish ratings and operating limitations based on power-supply requirements for the engine. Whether or not voltage and current limits are established for a component depends on the outcome of Special Condition no. 17 (Safety analysis), which examines the consequence of the component’s failure from high temperature. The FAA did not change this special condition as a result of this comment.

Special Condition No. 28, Rotor Locking Demonstration

The FAA proposed that Special Condition no. 28 would require the engine to demonstrate reliable rotor locking performance and that no hazardous engine effects will occur if the engine uses a rotor locking device to prevent shaft rotation.

Comment Summary: Wisk stated that this special condition does not contain a requirement that ensures the rotor lock feature cannot be enabled with a motor power set and also that its inadvertent activation is sufficiently unlikely that no major engine effect can occur. Wisk recommended that the FAA clarify if the term “hazardous” is being used in the context of system safety or in general terms.

Textron also requested that the FAA clarify the definition of “hazardous effects” and use that term consistently and recommended the following be added to Special Condition no. 28: “. . . that no hazardous effects as specified in Special Condition no. 17(d)(2) will occur.”

FAA Response: If magniX implements a rotor locking device in their engine design, Special Condition no. 28 will ensure the device exhibits reliable rotor locking performance and will not cause hazardous engine effects to preserve system safety. Special Condition no. 17 (Safety analysis) examines the

consequence of accidental rotor locking while the aircraft is in-flight and classifies the failure as either hazardous or major. The magniX engine will need to meet the requirements of this special condition and those of the safety analysis, which provide protection from inadvertent rotor locking.

The FAA clarified the terms “hazardous” and “hazardous engine effects” as they are used in Special Condition no. 28 by adding a reference to Special Condition no. 17(d)(2). The FAA changed final Special Condition no. 28 as a result of this comment.

Comment Summary: Textron requested that Special Condition no. 28 require magniX to consider the potential hazards from an automatic rotor locking system. Textron stated that if the engine is shut down during flight, and the locking device is automatic, the flight crew needs to have a means to remove the locking device and restart the engine without creating a hazard. The commenter recommended adding the following to Special Condition no. 28: “(b) When the locking device is in place, an indication shall be provided so that the crew will be able to retract the device while in flight.”

FAA Response: The FAA does not agree with the comment. magniX verifies rotor lock performance and reliability using the tests required by Special Condition no. 28. Typically, only rotorcraft have cockpit indications for locking devices. Those rotorcraft cockpit indications for locking devices are for main rotor transmissions, which are aircraft-level components. If an engine lock position indication is required to meet the aircraft safety objectives, the devices that notify the crew are part of the aircraft safety system. The FAA did not change these special conditions as a result of this comment.

Comment Summary: TCCA commented that this special condition should allow additional techniques to verify rotor locking performance. TCCA also suggested that the special condition requires a demonstration of reliable rotor “unlocking” performance.

FAA Response: Final Special Condition no. 28 has been changed to add rotor unlocking performance to the demonstration. However, allowing the use of a validated analysis would render the demonstration optional.

Special Condition No. 29, Teardown Inspection

The FAA proposed that Special Condition no. 29 would require magniX to perform either a teardown evaluation or a non-teardown evaluation based on

the criteria of Special Condition no. 29(a) or (b).

The FAA proposed that Special Condition no. 29(a) would require that the engine be disassembled after the endurance and durability demonstrations to verify each component remained within its service limits and in a condition for continued operation in accordance with § 33.4, *Instructions for Continued Airworthiness*.

The FAA proposed that Special Condition no. 29(b) would require magniX, for “non-teardown evaluations,” to establish life limits based on endurance and durability demonstrations.

In final Special Condition no. 29(b), magniX is required, for non-teardown evaluations, to account for engines, sub-assemblies, and components that cannot be disassembled without destroying the components. If teardown and inspection are not accomplished for components or assemblies after testing, the maintenance requirements for the engine are contingent on the demonstrated capabilities exhibited during the certification tests.

Comment Summary: GE recommended that the FAA clarify how life limits will be established if magniX cannot complete the teardown inspection of parts or components after the endurance and durability demonstrations. GE stated that the life limits should be documented in the engine’s airworthiness limitations or the engine’s ICA. TCCA also requested clarification about how life limits are established for parts and components that are not torn down after testing.

FAA Response: Special Condition no. 29 can have an effect on life limits. In the foregoing discussion of this condition, the FAA provided additional information to clarify how maintenance (such as life limits) is established for parts and components that are not torn down and inspected after testing. Also, the FAA changed final Special Condition no. 29 to require life limits resulting from this special condition to be documented in the ICA, in accordance with 14 CFR 33.4.

Comment Summary: Textron recommended that the FAA require inspections of electrical components in the controller after the endurance and durability demonstrations. Textron stated that, at a minimum, the FAA should require inspection of the controller’s fasteners, heat transfer components, dissimilar metallic junctions, and age or use affected electrical components.

FAA Response: The preamble of these special conditions explains that the

magniX engine consists of an electric motor, controller, and high-voltage systems. Special Condition no. 29(a) requires the engine to be completely torn down and inspected. Special Condition no. 29(b) contains provisions for engine components that are not disassembled for inspection. The FAA did not change these special conditions as a result of this comment.

Comment Summary: An individual commenter suggested potential long-term issues with main bearing lubrication related to grease life. The commenter stated that these issues might not be evident after completing a certification program.

FAA Response: In response to this comment, the FAA has changed final Special Condition no. 29(b) to require a life limit for the bearing lubricant if the bearing is not disassembled after testing. The FAA has changed the special condition as a result of this comment.

Comment Summary: TCCA recommended that the FAA mandate additional tests if the teardown inspection shows that part replacement is necessary.

FAA Response: The FAA does not concur with the comment. Special Condition nos. 32(b) and (b)(4) (General conduct of tests) already have the requested provisions for additional testing of parts that require replacement during a test or based on their condition at teardown inspection. The FAA made no changes to the special condition as a result of the comment.

Comment Summary: EASA commented that this Special Condition no. 29(b) was proposed to define the life limits of the tested components based on the endurance and durability tests. EASA stated this special condition was not aligned with ASTM F3338–18 and asked the FAA to elaborate on whether the selected limit is the highest or lowest one and how limits are compared if they are based on different test conditions.

FAA Response: ASTM F3338–18, section 5.22.1.5 establishes life limits for an electric engine based on the length of an endurance test if the engine is not torn down for inspection after the test. These special conditions require individual life limits to be established, based on endurance and durability demonstrations if individual components are not torn down and inspected after the tests. This special condition is consistent with the ASTM document EASA referenced in their comment. Because these special conditions apply to the magniX engine, the life limits will be based on the test conditions magniX uses to assess their engines. The FAA made no changes to

the special condition as a result of the comment.

Comment Summary: TCCA recommended that Special Condition no. 29 apply the non-teardown requirement to those components that need additional testing in accordance with §§ 33.53(a), *Engine system and component tests* or 33.91(a), *Engine system and component tests*. TCCA commented that, as the special condition is currently worded, some might apply the requirement only to internal engine parts. TCCA also requested that the FAA modify the special condition to require some post-test assessments for non-torn down components. TCCA also asked that the FAA clarify the requirement that “then the life limits for these components must be established based on the endurance and durability demonstrations.” TCCA contended that, as this requirement is currently worded, magniX could interpret it to mean that all internal parts of the electric engine would not need to be examined, including (Non-Destructive Testing) NDT, especially if there is no overhaul.

FAA Response: Special Condition no. 27 ensures that magniX addresses electric engine components that cannot be torn down for inspection. If the condition of these parts is questionable, then the requirements in Special Condition nos. 32(b) and 32(b)(4) can be applied for additional data to substantiate the life limit. These special conditions address TCCA’s comments. The FAA did not change the special condition as a result of this comment.

Special Condition No. 30, Containment

The FAA proposed that Special Condition no. 30 would require the engine to provide containment features that protect against likely hazards from rotating components, unless magniX can show, by test or validated analysis, that the margin to rotor burst does not justify the need for containment features. The intent of this special condition is to prevent hazardous engine effects from structural failure of rotating components and the rotating parts that are built into them.

Comment Summary: Textron stated that the wording in Special Condition no. 30(a) relating to the required burst margin for the rotor is vague. Textron suggested that the FAA incorporate the following change to Special Condition no. 30(a): “The design of the case surrounding rotating components must provide for the containment of the rotating components in the event of failure unless the applicant shows that the margin to rotor burst

unconditionally rules out the possibility of a rotor burst.”

FAA Response: The FAA agrees with the proposed change and has modified Special Condition no. 30(a) to incorporate Textron’s suggestion.

Comment Summary: Airbus stated that experience with electrical generators has shown that axial ejection of debris might induce severe damage to surroundings. Airbus stated that an axial containment demonstration is feasible for electric engines and generators, and therefore should be required by the FAA. Airbus said that this special condition should require magniX to show full containment capability, eliminating the need to identify forward- and aft-ejected debris in the engine installation manual. Airbus recommended that the FAA modify Special Condition no. 30(a) to state, “The design of the engine must provide for axial and radial containment of the rotating components . . .” Airbus also recommended the FAA modify Special Condition no. 30(b) to state, “If the margin to burst shows the case must have containment features in the event of failure, the case must provide axial and radial containment of the failed rotating components.”

FAA Response: These special conditions apply only to the magniX engine designs. Special Condition no. 30(b) is similar to § 33.94(a), *Blade containment and rotor unbalance tests*, and § 33.19(a), *Durability*, except this special condition includes the engine rotors. This special condition allows magniX to approach containment like turbine engines or provide full containment, as suggested in the comment. If a magniX engine design cannot contain the rotors, life limits will be applied in accordance with Special Condition no. 13 (Critical and life-limited parts). Therefore the FAA did not change this special condition as a result of this comment.

Comment Summary: EASA stated that the intent of the proposed Special Condition no. 30(b) is not clear, since that paragraph requests the case to provide containment of the failed rotating component while requesting that the applicant define the energy level, the trajectory, and the size of the released fragments. EASA asked the FAA to rewrite Special Condition no. 30(b) to be differentiated from Special Condition no. 30(a). EASA commented that Special Condition no. 30(b) should be dedicated to those cases where containment is not ensured.

FAA Response: Special Condition no. 30(b) provides a level of protection similar to that provided by FAA regulations that manage turbine engine

blade failures, except it includes the engine rotors. It precludes the release of high-energy debris radially outward of the rotors. If the magniX engines qualify for the provisions in Special Condition no. 30(b), fragments resulting from rotor damage, and that travel forward or aft of the containment plane, must have their energy levels and trajectories defined. The magniX engine configuration and declared containment capabilities would determine if compliance with Special Condition no. 30(b) is required. The FAA made no change to this special condition as a result of this comment.

Special Condition No. 31, Operation With a Variable Pitch Propeller

The FAA proposed that Special Condition no. 31 would require magniX to conduct functional demonstrations, including feathering, negative torque, negative thrust, and reverse thrust operations, as applicable, based on the propeller or fan’s variable pitch functions that are planned for use on these electric engines, with a representative propeller. Also, since these electric engines may be installed with a variable pitch propeller, the special condition associated with the operation with a variable pitch propeller or fan is necessary.

Comment Summary: TCCA commented that, in addition to the propeller control, there is a risk that an electric engine controller could fail and result in reverse engine rotation. TCCA suggested that the FAA add a special condition that considers and minimizes the potential for engine controller failures that could result in reverse engine rotation.

FAA Response: The FAA does not agree with the comment. Section 33.75(g)(2) provides a list of hazardous engine effects. The list includes thrust in the opposite direction. Special Condition no. 17(d)(2) defines hazardous engine effects as those in § 33.75(g)(2), with several additions specifically applicable to these electric engines. These special conditions address the failure described in the comment.

Comment Summary: TCCA recommended revising the Special Condition no. 31 text to read, “. . . with a representative propeller or fan. These demonstrations may be conducted in a manner acceptable to the Administrator as part . . .”.

FAA Response: The FAA has modified final Special Condition no. 31 to allow the Administrator to determine if a test is acceptable.

Special Condition No. 32, General Conduct of Tests

The FAA proposed that Special Condition no. 32 would require magniX to (1) include scheduled maintenance in the engine ICA before certification; (2) include any maintenance, in addition to the scheduled maintenance, that was needed during the test to satisfy the requirement; and (3) conduct additional tests that the Administrator finds necessary, warranted by the test results.

The term “excessive,” as it is used in proposed Special Condition nos. 32(b)(1) and (2), describes the frequency of unplanned engine maintenance and the frequency of unplanned test stoppages that are needed to address engine issues that prevent the engine from completing the tests. Deciding if unplanned maintenance or test stoppages are excessive requires an objective assessment of the reasons for the test interruptions. For example, magniX may not be able to simulate a realistic engine operating environment and may need to integrate test-enabling equipment to achieve the test goals. The test facility equipment may fail or cause an engine to fail during a test. Therefore, unplanned maintenance might not affect the certification test results, but if the FAA considers the maintenance or test stoppages to be “excessive,” additional testing or unforeseen ICA may be required to comply with the certification requirements.

Comment Summary: Rolls-Royce stated that it supports the clarifications in Special Condition no. 32(b) with the understanding that the term “excessive” in Special Condition nos. 32(b)(1) and 32(b)(2) allows for the rectification of some failures while the test continues. Rolls-Royce suggested that aircraft engines that operate using aviation fuel, operating at the extreme physical conditions required by the endurance tests, sometimes suffer a failure that is unrelated to the test conditions. The ability to review the failure with the FAA, rectify the failure, and continue the test is an important aspect of conducting these tests.

FAA Response: The FAA’s assessment of whether unplanned service and maintenance during testing are “excessive” could include a variety of factors, such as the causes of the stoppage, the effects of test facility equipment, difficulties in simulating a realistic engine operating environment, and whether the engine requires modifications to complete the test. The applicant could also show that unplanned maintenance did not affect the certification test results. The FAA

did not change this special condition as a result of this comment.

Comment Summary: TCCA commented that these special conditions do not address the emerging issue of single event effects, which the FAA is currently addressing via issue papers. TCCA recommended incorporating those issue papers into the special condition.

FAA Response: The FAA does not agree with the comment. The issue paper that TCCA referenced is applicable to engines that operate at high altitudes and high latitudes. Special Condition nos. 10 and 17 require magniX to account for the intended aircraft application. If magniX engines can operate at high altitudes and high latitudes, they could apply the referenced issue paper to the certification program. The FAA made no changes to these special conditions as a result of this comment.

Comment Summary: TCCA recommended that the FAA clarify the requirement in Special Condition no. 32(a) by including a reference to 14 CFR 33.4, *Instructions for continued airworthiness*.

FAA Response: The FAA has modified the special condition to add the requested reference to § 33.4 to clarify that magniX must provide the service and maintenance instructions in accordance with the ICA.

Applicability

As discussed above, these special conditions are applicable to the magniX magni350 and magni650 Model engines. Should magniX apply at a later date for a change to the type certificate to include another model on the same type certificate incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only magniX magni350 and magni650 model engines. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 33

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type

certification basis for magniX USA, Inc., (magniX), magni350 and magni650 model engines. The applicant must also comply with the certification procedures set forth in title 14, Code of Federal Regulations (14 CFR) part 21.

1. Applicability

Unless otherwise noted in these special conditions, the design must comply with the airworthiness standards for aircraft engines set forth in 14 CFR part 33, except those airworthiness standards specifically and explicitly applicable only to reciprocating and turbine aircraft engines.

2. Engine Ratings and Operating Limits

In addition to § 33.7(a), the design must comply with the following:

Ratings and operating limits must be established and included in the type certificate data sheet based on:

- (a) Shaft power, torque, rotational speed, and temperature for:
 - (1) Rated takeoff power;
 - (2) Rated maximum continuous power; and
 - (3) Rated maximum temporary power and associated time limit.
- (b) Duty Cycle and the rating at that duty cycle. The duty cycle must be declared in the engine type certificate data sheet.
- (c) Cooling fluid grade or specification.
- (d) Power-supply requirements.
- (e) Any other ratings or limitations that are necessary for the safe operation of the engine.

3. Materials

The engine design must comply with 14 CFR 33.15.

4. Fire Protection

The engine design must comply with 14 CFR 33.17.

In addition, high-voltage electrical wiring interconnect systems must be protected against arc faults. Any non-protected electrical wiring interconnects must be analyzed to show that arc faults do not cause a hazardous engine effect.

5. Durability

The engine design and construction must minimize the development of an unsafe condition of the engine between maintenance intervals, overhaul periods, or mandatory actions described in the applicable Instructions for Continued Airworthiness (ICA).

6. Engine Cooling

The engine design and construction must comply with § 33.21. In addition, if cooling is required to satisfy the safety

analysis as described in Special Condition no. 17, the cooling system monitoring features and usage must be documented in the engine installation manual.

7. Engine-Mounting Attachments and Structure

The engine-mounting attachments and related engine structures must comply with 14 CFR 33.23.

8. Accessory Attachments

The engine must comply with 14 CFR 33.25.

9. Overspeed

(a) A rotor overspeed must not result in a burst, rotor growth, or damage that results in a hazardous engine effect, as defined in Special Condition no. 17(d)(2). Compliance with this paragraph must be shown by test, validated analysis, or a combination of both. Applicable assumed rotor speeds must be declared and justified.

(b) Rotors must possess sufficient strength with a margin to burst above certified operating conditions and above failure conditions leading to rotor overspeed. The margin to burst must be shown by test, validated analysis, or a combination thereof.

(c) The engine must not exceed the rotor speed operational limitations that could affect rotor structural integrity.

10. Engine Control Systems

(a) Applicability.

The requirements of this special condition apply to any system or device that is part of the engine type design, that controls, limits, monitors, or protects engine operation and is necessary for the continued airworthiness of the engine.

(b) Engine control.

The engine control system must ensure the engine does not experience any unacceptable operating characteristics or exceed its operating limits, including in failure conditions where the fault or failure results in a change from one control mode to another, from one channel to another, or from the primary system to the back-up system, if applicable.

(c) Design assurance.

The software and complex electronic hardware, including programmable logic devices, must be—

(1) Designed and developed using a structured and systematic approach that provides a level of assurance for the logic commensurate with the hazard associated with the failure or malfunction of the systems in which the devices are located; and

(2) Substantiated by a verification methodology acceptable to the Administrator.

(d) Validation.

All functional aspects of the control system must be substantiated by test, analysis, or a combination thereof, to show that the engine control system performs the intended functions throughout the declared operational envelope.

(e) Environmental limits.

Environmental limits that cannot be adequately substantiated by endurance demonstration, validated analysis, or a combination thereof must be demonstrated by the system and component tests in Special Condition no. 27.

(f) Engine control system failures.

The engine control system must—

(1) Have a maximum rate of Loss of Power Control (LOPC) that is suitable for the intended aircraft application;

(2) When in the full-up configuration, be single fault tolerant, as determined by the Administrator, for electrical, electrically detectable, and electronic failures involving LOPC events;

(3) Not have any single failure that results in hazardous engine effects; and

(4) Not have any likely failure or malfunction that lead to local events in the intended aircraft application.

(g) System safety assessment.

The applicant must perform a system safety assessment. This assessment must identify faults or failures that affect normal operation, together with the predicted frequency of occurrence of these faults or failures. The intended aircraft application must be taken into account to assure the assessment of the engine control system safety is valid.

(h) Protection systems.

The engine control devices and systems' design and function, together with engine instruments, operating instructions, and maintenance instructions, must ensure that engine operating limits will not be exceeded in-service.

(i) Aircraft-supplied data.

Any single failure leading to loss, interruption, or corruption of aircraft-supplied data (other than power command signals from the aircraft), or aircraft-supplied data shared between engine systems within a single engine or between fully independent engine systems, must—

(1) Not result in a hazardous engine effect, as defined in Special Condition no. 17(d)(2), for any engine installed on the aircraft; and

(2) Be able to be detected and accommodated by the control system.

(j) Engine control system electrical power.

(1) The engine control system must be designed such that the loss, malfunction, or interruption of the control system electrical power source will not result in a hazardous engine effect, as defined in Special Condition no. 17(d)(2), the unacceptable transmission of erroneous data, or continued engine operation in the absence of the control function. The engine control system must be capable of resuming normal operation when aircraft-supplied power returns to within the declared limits.

(2) The applicant must identify and declare, in the engine installation manual, the characteristics of any electrical power supplied from the aircraft to the engine control system for starting and operating the engine, including transient and steady-state voltage limits, and any other characteristics necessary for safe operation of the engine.

11. Instrument Connection

The applicant must comply with 14 CFR 33.29(a), (e), and (g).

(a) In addition, as part of the system safety assessment of Special Condition no. 10(g), the applicant must assess the possibility and subsequent effect of incorrect fit of instruments, sensors, or connectors. Where practicable, the applicant must take design precautions to prevent incorrect configuration of the system.

(b) The applicant must provide instrumentation enabling the flight crew to monitor the functioning of the engine cooling system unless evidence shows that:

(1) Other existing instrumentation provides adequate warning of failure or impending failure;

(2) Failure of the cooling system would not lead to hazardous engine effects before detection; or

(3) The probability of failure of the cooling system is extremely remote.

12. Stress Analysis

(a) A mechanical, thermal, and electromagnetic stress analysis must show a sufficient design margin to prevent unacceptable operating characteristics and hazardous engine effects.

(b) Maximum stresses in the engine must be determined by test, validated analysis, or a combination thereof and must be shown not to exceed minimum material properties.

13. Critical and Life-Limited Parts

(a) The applicant must show, by a safety analysis or means acceptable to the Administrator, whether rotating or moving components, bearings, shafts,

static parts, and non-redundant mount components should be classified, designed, manufactured, and managed throughout their service life as critical or life-limited parts.

(1) *Critical part* means a part that must meet prescribed integrity specifications to avoid its primary failure, which is likely to result in a hazardous engine effect as defined in Special Condition no. 17(d)(2) of these special conditions.

(2) *Life-limited part* means a rotor and major structural static part, the failure of which can result in a hazardous engine effect due to low-cycle fatigue (LCF) mechanism or any LCF driven mechanism coupled with creep. A life limit is an operational limitation that specifies the maximum allowable number of flight cycles that a part can endure before the applicant must remove it from the engine.

(b) In establishing the integrity of each critical part or life-limited part, the applicant must provide to the Administrator the following three plans for approval:

(1) An engineering plan that establishes and maintains that the combination of loads, material properties, environmental influences, and operating conditions, including the effects of engine parts influencing these parameters, are sufficiently well-known and predictable by validated analysis, test, or service experience. The engineering plan must ensure each critical part or life-limited part is withdrawn from service at an approved life before hazardous engine effects can occur. The engineering plan must establish activities to be executed both pre- and post-certification. In addition to the activities that must be completed prior to certification, including a reporting system that flows, back to magniX, problematic issues that develop in engines while they operate in-service, to be addressed by the design process. magniX must perform appropriate damage-tolerance assessments to address the potential for failure from material, manufacturing, and service-induced anomalies within the approved life of the part. The approved life must be published in the mandatory ICA.

(2) A manufacturing plan that identifies the specific manufacturing definition (drawings, procedures, specifications, etc.) necessary for the manufacturer to consistently produce critical or life-limited parts with the design attributes required by the engineering plan.

(3) A service-management plan defines in-service processes for maintenance and repair of critical or life-limited parts that maintain

attributes consistent with those required by the engineering plan. These processes must be part of the mandatory ICA.

14. Lubrication System

(a) The lubrication system must be designed and constructed to function properly between scheduled maintenance intervals in all flight attitudes and atmospheric conditions in which the engine is expected to operate.

(b) The lubrication system must be designed to prevent contamination of the engine bearings and lubrication system components.

(c) The applicant must demonstrate by test, validated analysis, or a combination thereof, the unique lubrication attributes and functional capability of (a) and (b).

15. Power Response

The design and construction of the engine, including its control system, must enable an increase—

(a) From the minimum power setting to the highest-rated power without detrimental engine effects;

(b) From the minimum obtainable power while in-flight and while on the ground to the highest-rated power within a time interval determined to be safe for aircraft operation; and

(c) From the minimum torque to the highest-rated torque without detrimental engine or aircraft effects to ensure aircraft structural integrity or aircraft aerodynamic characteristics are not exceeded.

16. Continued Rotation

If the design allows any of the engine main rotating systems to continue to rotate after the engine is shut down while in-flight, this continued rotation must not result in any hazardous engine effects, as specified in Special Condition no. 17(d)(2).

17. Safety Analysis

(a) The applicant must comply with § 33.75(a)(1) and (a)(2) using the failure definitions in Special Condition no. 17(d).

(b) If the failure of such elements is likely to result in hazardous engine effects, then the applicant may show compliance by reliance on the prescribed integrity requirements such as § 33.15, Special Condition no. 9, Special Condition no. 13, or combinations thereof, as applicable. The failure of such elements and associated prescribed integrity requirements must be stated in the safety analysis.

(c) The applicant must comply with § 33.75(d) and (e) using the failure definitions in Special Condition no. 17(d) of these special conditions.

(d) Unless otherwise approved by the Administrator, the following definitions apply to the engine effects when showing compliance with this condition:

(1) A minor engine effect does not prohibit the engine from meeting its certificated performance requirements and the intended functions in a manner consistent with § 33.28(b)(1)(i), § 33.28(b)(1)(iii) and § 33.28 (b)(1)(iv), and the engine complies with the operability requirements such as Special Condition no. 15 (Power response), Special Condition no. 25 (Operation demonstration), and Special Condition no. 31 (Operation with a variable pitch propeller), as appropriate.

(2) The engine effects in § 33.75(g)(2) are hazardous engine effects with the addition of:

(i) Electrocution of the crew, passengers, operators, maintainers, or others; and

(ii) Blockage of cooling systems that are required for the engine to operate within temperature limits.

(3) Any other engine effect is a major engine effect.

(e) The intended aircraft application must be taken into account to assure the analysis of the engine system safety is valid.

18. Ingestion

(a) Ingestion from likely sources (foreign objects, birds, ice, hail) must not result in hazardous engine effects defined by Special Condition no. 17(d)(2), or unacceptable power loss.

(b) Rain ingestion must not result in an abnormal operation such as shutdown, power loss, erratic operation, or power oscillations throughout the engine operating range.

(c) If the design of the engine relies on features, attachments, or systems that the installer may supply, for the prevention of unacceptable power loss or hazardous engine effects following potential ingestion, then the features, attachments, or systems must be documented in the engine installation manual.

(d) Ingestion sources that are not evaluated must be declared in the engine installation manual.

19. Liquid Systems

(a) Each liquid system used for lubrication or cooling of engine components must be designed and constructed to function properly in all flight attitudes and atmospheric conditions in which the engine is expected to operate.

(b) If a liquid system used for lubrication or cooling of engine components is not self-contained, the

interfaces to that system must be defined in the engine installation manual.

(c) The applicant must establish by test, validated analysis, or a combination of both that all static parts subject to significant gas or liquid pressure loads will not:

(1) Exhibit permanent distortion beyond serviceable limits or exhibit leakage that could create a hazardous condition when subjected to normal and maximum working pressure with margin.

(2) Exhibit fracture or burst when subjected to the greater of maximum possible pressures with margin.

(d) Compliance with Special Condition no. 19(c) must take into account:

(1) The operating temperature of the part;

(2) Any other significant static loads in addition to pressure loads;

(3) Minimum properties representative of both the material and the processes used in the construction of the part; and

(4) Any adverse physical geometry conditions allowed by the type design, such as minimum material and minimum radii.

(e) Approved coolants and lubricants must be listed in the engine installation manual.

20. Vibration Demonstration

(a) The engine must be designed and constructed to function throughout its normal operating range of rotor speeds and engine output power, including defined exceedances, without inducing excessive stress in any engine parts because of vibration and without imparting excessive vibration forces to the aircraft structure.

(b) Each engine design must undergo a vibration survey to establish that the vibration characteristics of those components that may be subject to induced vibration are acceptable throughout the declared flight envelope and engine operating range for the specific installation configuration. The possible sources of the induced vibration that the survey must assess are mechanical, aerodynamic, acoustical, or electromagnetic. This survey must be shown by test, validated analysis, or a combination thereof.

21. Overtorque

When approval is sought for a transient maximum engine overtorque, the applicant must demonstrate by test, validated analysis, or a combination thereof, that the engine can continue operation after operating at the maximum engine overtorque condition

without maintenance action. Upon conclusion of overtorque tests conducted to show compliance with this special condition, or any other tests that are conducted in combination with the overtorque test, each engine part or individual groups of components must meet the requirements of Special Condition no. 29.

22. Calibration Assurance

Each engine must be subjected to calibration tests to establish its power characteristics and the conditions both before and after the endurance and durability demonstrations specified in Special Conditions nos. 23 and 26.

23. Endurance Demonstration

The applicant must subject the engine to an endurance demonstration, acceptable to the Administrator, to demonstrate the engine's limit capabilities.

The endurance demonstration must include increases and decreases of the engine's power settings, and dwellings at the power settings for durations that produce the extreme physical conditions the engine experiences at rated performance levels, operational limits, and at any other conditions or power settings that are required to verify the limit capabilities of the engine.

24. Temperature Limit

The engine design must demonstrate its capability to endure operation at its temperature limits plus an acceptable margin. The applicant must quantify and justify to the Administrator the margin at each rated condition. The demonstration must be repeated for all declared duty cycles and associated ratings, and operating environments, that would impact temperature limits.

25. Operation Demonstration

The engine design must demonstrate safe operating characteristics, including but not limited to power cycling, starting, acceleration, and overspeeding throughout its declared flight envelope and operating range. The declared engine operational characteristics must account for installation loads and effects.

26. Durability Demonstration

The engine must be subjected to a durability demonstration to show that each part of the engine has been designed and constructed to minimize any unsafe condition of the system between overhaul periods or between engine replacement intervals if the overhaul is not defined. This test must simulate the conditions in which the

engine is expected to operate in-service, including typical start-stop cycles.

27. System and Component Tests

The applicant must show that systems and components will perform their intended functions in all declared environmental and operating conditions.

28. Rotor Locking Demonstration

If shaft rotation is prevented by locking the rotor(s), the engine must demonstrate:

(a) Reliable rotor locking performance;

(b) Reliable unlocking performance; and

(c) That no hazardous engine effects, as specified in Special Condition no. 17(d)(2), will occur.

29. Teardown Inspection

The applicant must comply with either (a) or (b) as follows:

(a) Teardown evaluation.

(1) After the endurance and durability demonstrations have been completed, the engine must be completely disassembled. Each engine component and lubricant must be within service limits and eligible for continued operation in accordance with the information submitted for showing compliance with § 33.4, Instructions for Continued Airworthiness.

(2) Each engine component having an adjustment setting and a functioning characteristic that can be established independent of installation on or in the engine must retain each setting and functioning characteristic within the established and recorded limits at the beginning of the endurance and durability demonstrations.

(b) Non-Teardown evaluation.

If a teardown is not performed for all engine components, then the life limits for these components and lubricants must be established based on the endurance and durability demonstrations and documented in the ICA in accordance with § 33.4.

30. Containment

The engine must provide containment features that protect against likely hazards from rotating components as follows—

(a) The design of the case surrounding rotating components must provide for the containment of the rotating components in the event of failure, unless the applicant shows that the margin to rotor burst precludes the possibility of a rotor burst.

(b) If the margin to burst shows that the case must have containment features in the event of failure, the case must provide for the containment of the failed

rotating components. The applicant must define by test, validated analysis, or a combination thereof, and document in the engine installation manual, the energy level, trajectory, and size of fragments released from damage caused by the main rotor failure, and that pass forward or aft of the surrounding case.

31. Operation With a Variable Pitch Propeller

The applicant must conduct functional demonstrations including feathering, negative torque, negative thrust, and reverse thrust operations, as applicable, with a representative propeller. These demonstrations may be conducted in a manner acceptable to the Administrator as part of the endurance,

durability, and operation demonstrations.

32. General Conduct of Tests

(a) Maintenance of the engine may be made during the tests in accordance with the service and maintenance instructions submitted in compliance with § 33.4.

(b) The applicant must subject the engine or its parts to maintenance and additional tests that the Administrator finds necessary if—

- (1) The frequency of the service is excessive;
- (2) The number of stops due to engine malfunction is excessive;
- (3) Major repairs are needed; or

(4) Replacement of a part is found necessary during the tests or due to the teardown inspection findings.

(c) Upon completion of all demonstrations and testing specified in these special conditions, the engine and its components must be—

- (1) Within serviceable limits;
- (2) Safe for continued operation; and
- (3) Capable of operating at declared ratings while remaining within limits.

Issued in Kansas City, Missouri, on September 10, 2021.

Patrick R. Mullen,

Manager, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service.

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S. 272/P.L. 117-40

Congressional Budget Justification Transparency Act of 2021 (Sept. 24, 2021; 135 Stat. 337)

S. 325/P.L. 117-41

To amend the Alyce Spotted Bear and Walter Soboleff

Commission on Native Children Act to extend the deadline for a report by the Alyce Spotted Bear and Walter Soboleff Commission on Native Children, and for other purposes. (Sept. 24, 2021; 135 Stat. 341)
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